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Clinical Appropriateness Guidelines

Sleep Disorder Management

Appropriate Use Criteria: Diagnostic and Treatment Management

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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. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

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

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. 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. 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.

General Clinical Guideline

Clinical Appropriateness Framework

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

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

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

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

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

Additionally, either of the following may apply:

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

Repeat Diagnostic Intervention

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

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

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

- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

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

SLEEP DISORDER DIAGNOSTIC MANAGEMENT

Polysomnography and Home Sleep Apnea Testing

Coding

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

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

CPT/HCPCS

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

General Information

Scope of the Guideline

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

- Obstructive sleep apnea (OSA) – the most common of the sleep disorders
- Central sleep apnea (CSA)
- Narcolepsy
- Parasomnias and related sleep movement disorders including:

    - Confusion arousals
    - Somnambulism (sleepwalking)
    - Sleep terrors
    - Rapid eye movement (REM) sleep behavior disorder
    - Sleep-related epilepsy
    - Sleep bruxism
    - Sleep enuresis (bed wetting)
    - Periodic limb movement disorder (PLMD)
- Nocturnal oxygen desaturation

Overview

Obstructive sleep apnea (OSA) is a common disorder affecting up to 2%–4% of the population. Many patients with OSA remain undiagnosed. OSA is characterized by repeated interruption of breathing during sleep (apnea) or by episodes of diminished airflow to the lungs (hypopnea). These episodes are the result of narrowing or closure of the upper airway during sleep. The clinical hallmarks of OSA are reported loud snoring or apnea during sleep (if the patient has a bed partner), or patient complaints of frequent awakenings with gasping or choking. This fragmentation of sleep leads to daytime sleepiness and other symptoms including morning headache, poor concentration, memory impairment, irritability, decreased libido, and nocturia. Although OSA may occur in all age groups, it is most common in patients between 40 and 70 years old. The incidence of OSA in obese patients is considerably higher than in non-obese individuals. OSA is associated with higher mortality because patients with OSA are more likely to have cardiac arrhythmias, coronary artery disease, congestive heart failure, stroke, diabetes, and treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications). Because of daytime sleepiness, deaths related to motor vehicle accidents are also more common in patients with OSA.

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

Sleep testing may be classified as follows:

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

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

Regardless of the site of testing, sleep studies objectively measure the degree of respiratory disturbance during sleep. Episodes of **apnea** (cessation of breathing lasting at least 10 seconds) and **hypopnea** (reduction, but not a cessation of air exchange, with an associated fall in oxygen saturation [at least 3% to 4%] or arousal) are recorded. The apnea/hypopnea index (AHI) is the average number of apneic and hypopneic episodes per hour based on a minimum of 2 hours of recording.

The respiratory disturbance index (RDI), a similar (but not identical) parameter, is the average number of apneic, hypopneic and respiratory effort related arousals (RERAS) per hour based on at least 2 hours of recording. For the purposes of this guideline, the terms AHI and RDI can be used interchangeably.

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

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

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

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

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

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

Clinical Indications

Home (Unattended) Sleep Studies

Note: Home sleep studies performed with Type II and Type III devices (as defined above) and devices which utilize the combination of peripheral arterial tone (PAT), actigraphy, EKG/heart rate and oxygen saturation are considered medically necessary when the criteria below are met. Type IV devices not meeting this description are considered to be not medically necessary in all clinical scenarios.

Table 1: Contraindications to Home Sleep Study

1	Patient is 18 years old or younger
2	Moderate or severe chronic obstructive pulmonary disease (COPD) – forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) less than or equal to 0.7 and FEV1 less than 80% of predicted
3	Moderate or severe congestive heart failure – New York Heart Association (NYHA) class III or IV
4	Congestive heart failure with a history of ventricular fibrillation or sustained ventricular tachycardia in a patient who does not have an implanted defibrillator
5	Cognitive impairment (inability to follow simple instructions) resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task
6	Physical impairment resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task
7	The patient has a suspected or established diagnosis of **ONE** of the following conditions (a-f): a) central sleep apnea, b) periodic limb movement disorder (PLMD), c) narcolepsy, d) idiopathic hypersomnia, e) parasomnia (except bruxism and somniloqui [sleep talking]), f) nocturnal seizures. In order to support the suspicion of PLMD in this context, **ONE** of the following (i-vi) must be documented: i) pregnancy, ii) renal failure, iii) iron deficiency anemia, iv) peripheral neuropathy, v) use of antidepressant or antipsychotic medications, or vi) continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep testing.
8	Previous technically suboptimal home sleep study in **EITHER** of the following scenarios (a or b): 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; **OR** Two nights of study attempted, but the study remains suboptimal after 2 nights
9	Previous 2-night home sleep study did not diagnose OSA in a patient with ongoing clinical suspicion of OSA
10	Patient is oxygen dependent for any reason
11	History of stroke within the preceding 30 days
12	Chronic opiate narcotic use, when discontinuation is not an option. Diagnostic sleep testing for patients using opiate narcotics for acute self-limited conditions should ideally be deferred until the medications have been stopped.
13	Body mass index (BMI) >33 and elevated serum bicarbonate level >28 mmol/L
14	Established diagnosis of obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires either an increase in arterial PCO2 (or surrogate measure) to >55 mmHg for at least 10 minutes or a >10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes.

Suspected OSA

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

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

Established OSA – follow-up home sleep studies

A patient with established diagnosis of OSA should have a follow-up home sleep study if **EITHER** of the following applies **AND** there is no contraindication to a home sleep study (as outlined in Table 1 above):

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

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

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

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

1. Observed apneas during sleep; **OR**
2. A combination of **at least TWO** of the following (a–e):
    a. Excessive daytime sleepiness evidenced by an Epworth sleepiness scale score greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
    b. Habitual snoring or gasping/choking episodes associated with awakenings;
    c. Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications);
    d. Obesity, defined as a body mass index greater than 30 kg/m2 or increased neck circumference defined as greater than 17 inches in men or greater than 16 inches in women;

e. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease; **OR**

3. History of stroke, transient ischemic attack, coronary artery disease, or sustained tachycardic or bradycardic arrhythmias in patients who meet one of the criteria in 2a–e above.

Suspected sleep disorder other than OSA

An in-lab supervised sleep study is appropriate when there is suspicion of **ANY** of the following (1–7):

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

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

A patient with established diagnosis of OSA or other sleeping disorders should have a follow-up in-lab sleep study if **EITHER** of the following (1 or 2) applies **AND** the patient has a contraindication to a home sleep study (as outlined in Table 1 above):

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

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

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

***Contraindications to APAP include ANY of the following (1-7):**

1. Age 18 years or younger
2. Congestive heart failure
3. Chronic obstructive pulmonary disease

4. Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
5. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
6. Obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires **EITHER** an increase in arterial PCO2 (or surrogate measure) to >55 mmHg for at least 10 minutes **OR** a >10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value **EXCEEDING** 50 mmHg for at least 10 minutes.
7. Chronic narcotic use

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

Suspected sleep disorder (OSA or other)

An in-lab sleep (attended) study is indicated if the patient meets **ANY** of the following criteria (1–11):

1. Habitual snoring in association with **ONE** or more of criteria a–e below:
    a. Restless or disturbed sleep
    b. Behavioral disturbance or learning disorders including deterioration in academic performance, attention deficit disorder, hyperactivity
    c. Frequent awakenings
    d. Enuresis (bedwetting)
    e. Growth retardation or failure to thrive; **OR**
2. Excessive daytime somnolence or altered mental status not explained by other conditions; **OR**
3. Polycythemia not explained by other conditions; **OR**
4. Cor pulmonale not explained by other conditions; **OR**
5. Witnessed apnea with duration greater than 2 respiratory cycles; **OR**
6. Labored breathing during sleep; **OR**
7. Hypertrophy of the tonsils or adenoids in patients at significant surgical risk such that the exclusion of OSA would allow avoidance of surgery; **OR**
8. Suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disease or chest wall deformities; **OR**
9. Clinical evidence of a sleep-related breathing disorder in infants who have experienced an apparent life-threatening event; **OR**
10. For exclusion of OSA in a patient who has undergone adenotonsillectomy for suspected OSA more than 8 weeks previously; **OR**
11. The initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing.

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

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

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

2. The patient has undergone adenotonsillectomy more than 8 weeks previously for management of established OSA; **OR**
3. To re-evaluate the diagnosis of OSA and need for continued PAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study; **OR**
4. To titrate CPAP or BPAP in a patient whose diagnostic study confirms that the patient is a candidate for positive airway pressure therapy and split-night study has not been performed or was inadequate; **OR**
5. The initial sleep study has led to a diagnosis other than OSA and the repeat study is requested because of a change in clinical status or to assess efficacy after a change in therapy.

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Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing

Coding

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

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

CPT/HCPCS

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

General Information

Scope of the Guideline

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

Overview

Narcolepsy

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

Idiopathic hypersomnia

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

Multiple sleep latency testing (MSLT)

During MSLT the patient is provided several opportunities to nap. Physiologic parameters recorded include electroencephalography (EEG), electrooculography (EOG), mental or submental electromyography (EMG), and electrocardiography (ECG). The sleep latency (time to onset of sleep), and the presence of sleep onset rapid eye movement (SOREM) events are evaluated. Initial MSLT occasionally fails to identify narcolepsy. Repeat testing may be necessary when the initial results are negative or ambiguous and the clinical history indicates a diagnosis

of narcolepsy. MSLT should not be performed while the patient is taking (or within two weeks of stopping) stimulant medications, sedatives or rapid eye movement (REM) suppressing medications.

Maintenance of wakefulness testing (MWT)

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

Clinical Indications

Multiple Sleep Latency Testing and/or Maintenance of Wakefulness Testing

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

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

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

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

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

1. Daytime hypersomnolence has been present for at least 8 weeks
2. The patient has at least **ONE** of the following (a-e):
    a. Difficult morning awakening
    b. Prolonged night sleep
    c. Sleep drunkenness
    d. Frequent non-refreshing daytime naps
    e. The patient has undergone polysomnography since the onset of symptoms (PSG) and symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

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SLEEP DISORDER TREATMENT MANAGEMENT

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

Coding

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

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

CPT/HCPCS

E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Single level continuous positive airway pressure device or auto-titrating continuous positive airway pressure
E1399	Durable medical equipment, miscellaneous
A4604	Tubing with heating element
A7027	Combination Oral/Nasal Mask used with positive airway pressure device, each
A7028	Oral Cushion, Replacement for Combination Oral/Nasal Mask, each
A7029	Nasal Pillows, Replacement for Combination Oral/Nasal Mask, pair
A7030	Full Face Mask used with positive airway pressure device, each
A7031	Face Mask Cushion, Replacement for Full Face Mask
A7032	Replacement Cushion for Nasal Application Device
A7033	Replacement Pillows for Nasal Application Device, pair
A7034	Nasal Interface (mask or cannula type), used with positive airway pressure device, with/without head strap
A7035	Headgear
A7036	Chinstrap
A7037	Tubing
A7038	Filter, disposable
A7039	Filter, non-disposable
A7044	Oral Interface for Positive Airway Pressure Therapy
A7045	Replacement Exhalation Port for PAP Therapy
A7046	Water chamber for humidifier, replacement, each

General Information

Scope of the Guideline

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

Overview

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

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

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

Clinical Indications

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

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

A. Home- or lab-based sleep study demonstrates **ONE** of the following (1–2):

   1. AHI greater than or equal to 15

2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke

AND

B. Appropriate CPAP level has been determined from **ONE** of the following (1–5):

1. Split-night sleep study
2. Whole-night lab-based titration study following a diagnostic lab study at which the CPAP level was not determined
3. Whole-night lab-based titration study in a patient in whom APAP is contraindicated*
4. APAP titration trial
5. Whole-night lab-based titration study when home, unmonitored APAP titration was unsuccessful

***Contraindications to APAP include ANY of the following (1-7):**

1. Age 18 years or younger
2. Congestive heart failure
3. Chronic obstructive pulmonary disease
4. Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
5. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
6. Obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires **EITHER** an increase in arterial PCO2 (or surrogate measure) to >55 mmHg for at least 10 minutes **OR** a >10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value **EXCEEDING** 50 mmHg for at least 10 minutes.
7. Chronic narcotic use

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

A. A lab-based sleep study demonstrating AHI of at least **ONE** and appropriate CPAP titration has been performed

AND

B. **ONE** of the following (1–4) is true:

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

Treatment with APAP is appropriate when a patient meets condition A and either B or C below

A. Home or lab-based sleep study demonstrates **ONE** of the following (1–2):

1. AHI greater than or equal to 15

2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke

AND EITHER

B. The patient has **NONE** of the following contraindications (1–7) to the use of APAP:

1. Age 18 years or younger
2. Congestive heart failure
3. Chronic obstructive pulmonary disease
4. Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
5. Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
6. Obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires **EITHER** an increase in arterial PCO2 (or surrogate measure) to >55 mmHg for at least 10 minutes **OR** a >10 mmHg increase in arterial PCO2 (or surrogate measure) during sleep (compared to an awake supine value) to a value **EXCEEDING** 50 mmHg for at least 10 minutes.
7. Chronic narcotic use

OR

C. In the opinion of the treating provider, APAP is preferable to in-lab titration

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

Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days for the first year of therapy and annually thereafter. Compliance is defined as follows:

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

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Bi-Level Positive Airway Pressure Devices

Coding

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

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

CPT/HCPCS

E0470	Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with non-invasive interface (nasal or facial mask)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with non-invasive interface (nasal or facial mask)
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E1399	Durable medical equipment, miscellaneous
A4604	Tubing with heating element
A7027	Combination Oral/Nasal Mask used with positive airway pressure device, each
A7028	Oral Cushion, Replacement for Combination Oral/Nasal Mask, each
A7029	Nasal Pillows, Replacement for Combination Oral/Nasal Mask, pair
A7030	Full Face Mask used with positive airway pressure device, each
A7031	Face Mask Cushion, Replacement for Full Face Mask
A7032	Replacement Cushion for Nasal Application Device
A7033	Replacement Pillows for Nasal Application Device, pair
A7034	Nasal Interface (mask or cannula type), used with positive airway pressure device, with/without head strap
A7035	Headgear
A7036	Chinstrap
A7037	Tubing
A7038	Filter, disposable
A7039	Filter, non-disposable
A7044	Oral Interface for Positive Airway Pressure Therapy
A7045	Replacement Exhalation Port for PAP Therapy
A7046	Water chamber for humidifier, replacement, each

General Information

Scope of the Guideline

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

Overview

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

For patients requiring treatment with BPAP, pressure levels need to be titrated to each patient's particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the titration study in a single night. This approach, known as split-night study, may be used when the apnea/hypopnea index (AHI) exceeds 20 per hour based on the first 2 hours of testing. Those who do not meet criteria for split-night protocol require either a second overnight titration study or temporary use of auto-titrating BPAP as a means of BPAP titration. Titration may not be required if auto-titrating BPAP is selected as the long-term therapeutic approach.

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

Clinical Indications

Bi-Level Positive Airway Pressure Devices (BPAP)

BPAP (without back-up rate feature)

Appropriate for patients with OSA who have failed CPAP/APAP or require supplemental ventilatory support due to a hypoventilation syndrome

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

Appropriate for patients with established CSA diagnosed by an in-lab sleep study when **BOTH** of the following (a and b) apply:

a. OSA has been excluded or treated; **AND**

b. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO_2)

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

Appropriate in the management of patients with severe COPD demonstrating **EITHER** of the following (a or b):

a. $PaCO_2$ measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO_2 is 52 mmHg or greater; **OR**

b. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes oxygen at 2L per minute or his/her usual FiO_2 (whichever is higher)

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

Appropriate in the management of patients with certain restrictive thoracic disorders when **BOTH** a and b below are true:

a. The patient has an established diagnosis of a progressive neuromuscular disease, e.g., amyotrophic lateral sclerosis (ALS) or a severe thoracic cage abnormality; **AND**

b. **ONE** of the following statements is true:

- PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO2 is 45 mmHg or greater
- Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes his/her usual FiO2
- Maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

Ongoing treatment with BPAP

Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days for the first year of treatment and annually thereafter. Compliance is defined as follows:

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

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Management of Obstructive Sleep Apnea using Oral Appliances

Coding

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

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

CPT/HCPCS

E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

General Information

Scope of the Guideline

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

Overview

In addition to lifestyle changes, (weight loss, avoidance of alcohol and sedatives, etc.) positive airway pressure (PAP) therapy is considered to be the first-line approach to the management of patients with all degrees of obstructive sleep apnea. For patients who have mild or moderate OSA, certain OAs may be used as an alternative to PAP therapy in patients who are intolerant of PAP therapy, those for whom PAP therapy is ineffective, and those who prefer to consider an OA rather than PAP as a first line therapy. It is highly recommended that the decision to use an OA in the management of OSA should follow consultation with a sleep medicine specialist. Custom made oral appliances require a prescription from a medical provider.

Mandibular repositioning appliances (MRA) cover the upper and lower teeth and hold the mandible in an advanced position with respect to the resting position. Tongue retaining devices (TRD) hold only the tongue in a forward position with respect to the resting position, without mandibular repositioning. Both appliances change the contour of the upper airway such that the likelihood of airway collapse during sleep is reduced. When MRAs are used in the management of OSA, they must comply with all of the following specifications as outlined by Centers for Medicare & Medicaid Services (CMS):

- Have a fixed mechanical hinge at the sides, front, or palate
- Have a mechanism that allows the mandible to be advanced in increments of one millimeter or less
- Be able to protrude the mandible beyond the front teeth at maximum protrusion
- Be adjustable by the beneficiary in increments of one millimeter or less
- Retain the adjustment setting when removed

- Maintain mouth position during sleep so as to prevent dislodging the device.

Clinical Indications

Custom Fabricated Oral Appliances (CPT E0486)

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

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

B. **ONE** of the following (a-c) applies:

a. The patient is not a candidate for positive airway pressure therapy; **OR**

b. Positive airway pressure therapy has not been effective despite a 45-day trial and participation in a positive airway pressure compliance program; **OR**

c. The patient has tried continuous positive airway pressure (CPAP) but has not been compliant despite a 45-day trial and participation in a positive airway pressure compliance program.

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

A. At least **ONE** of the following:

a. AHI greater than or equal to 15 and less than or equal to 30; **OR**

b. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke; **AND**

B. At least **ONE** of the following:

a. The patient is not a candidate for positive airway pressure therapy; **OR**

b. Positive airway pressure therapy has not been effective despite a 45-day trial and participation in a positive airway pressure compliance program; **OR**

c. The patient has tried CPAP but has not been compliant despite a 45-day trial and participation in a positive airway pressure compliance program; **OR**

d. The patient prefers to use an OA rather than PAP as the initial therapy; **AND**

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

Prefabricated Oral Appliances (CPT E0485)

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

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Glossary

AHI	Apnea/hypopnea index
ALS	Amyotrophic lateral sclerosis
APAP	Automatically titrating positive airway pressure
BMI	Body mass index
BPAP	Bi-level positive airway pressure
CHF	Congestive heart failure
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CSA	Central sleep apnea
EEG	Electroencephalogram
EKG	Electrocardiogram
EMG	Electromyogram
EOG	Electrooculogram
FEV1	Forced expiratory volume in 1 second
FiO_2	Fraction of inspired oxygen
FVC	Forced vital capacity
HNS	Hypoglossal nerve stimulation
MRA	Mandibular repositioning appliance
MSLT	Multiple sleep latency testing
MWT	Maintenance of wakefulness testing
NYHA	New York Heart Association
OA	Oral appliance
OSA	Obstructive sleep apnea
$PaCO_2$	Partial pressure of carbon dioxide in arterial blood
PAP	Positive airway pressure
PLMD	Periodic limb movement disorder
PSG	Polysomnography
RDI	Respiratory disturbance index
REM	Rapid eye movement
RERA	Respiratory effort related arousal
TRD	Tongue retaining device

History

Status	Review Date	Effective Date	Action
Reaffirmed	12/03/2020	Unchanged	Independent Multispecialty Physician Panel (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.