Noninvasive Positive Pressure Ventilation

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Noninvasive Positive Pressure Ventilation (NPPV) may be used to treat a number of conditions, including sleep-related breathing disorders and chronic lung disease. Sleep-related breathing disorders, such as obstructive sleep apnea, are conditions in which abnormal breathing events during sleep are associated with negative impacts on a person's health. Chronic lung diseases, such as chronic obstructive pulmonary disease (COPD), affect the ability of a person to breathe in oxygen and breathe out carbon dioxide. When needed to treat these conditions, NPPV is accomplished by using Positive Airway Pressure (PAP) devices. PAP devices are non-invasive and improve oxygenation and gas exchange in the lungs by producing airflow through oral, nasal, or combination oronasal masks.

Prior to initiation of PAP therapy, a sleep study (e.g. home sleep test, attended nocturnal polysomnography) coupled with the clinically appropriate lung testing (e.g. arterial blood gas, pulmonary function testing) is required to confirm the diagnosis, level of severity, and most appropriate treatment. The device must also be prescribed by a board-certified pulmonary specialist or board-certified sleep medicine practitioner.

Definitions

"Sleep-Related Breathing Disorders" are conditions in which abnormal breathing events occur during sleep include:

1. Obstructive Sleep Apnea (OSA)- sleep-related breathing disorder that occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway. This causes reduced or complete halt in airflow despite an ongoing effort to breathe.
2. Central Sleep Apnea (CSA) syndromes are caused by post-hyperventilation central apnea, which may be triggered by a variety of clinical conditions, and central apnea secondary to hypoventilation, which has been described with opioid use as per American Academy of Sleep Medicine. These types include but not limited to:
    a. Primary Central Sleep Apnea
    b. CSA due to Cheyne-Stokes breathing pattern
    c. CSA due to Medical Condition Not Cheyne-Stokes
    d. CSA due to Drug or Substance
    e. Primary Sleep Apnea of Infancy
3. Complex Sleep Apnea (i.e., Treatment-Emergent Central Sleep Apnea) - defined by Centers for Medicare and Medicaid Services as central apnea specifically identified by the persistence or emergence of central apneas or hypopneas during the initiation of CPAP or an E0470 device despite obstructive respiratory events have been significantly reduced. Complex sleep apnea is distinct as obstructive or mixed apnea is present without treatment and can be worsened during positive airway treatment.
4. Sleep-Related Hypoventilation Syndrome (SRHS) - is a syndrome with the presence of elevated PaCO2 levels either directly (by arterial blood gas measurement) or indirectly (by end-tidal CO2 or transcutaneous CO2 measurements) and includes the following disorders:
    a. Obesity hypoventilation syndrome
    b. Congenital central alveolar hypoventilation syndrome
    c. Late-onset central hypoventilation with hypothalamic dysfunction
    d. Idiopathic central alveolar hypoventilation
    e. Sleep-related hypoventilation due to a medication or substance
    f. Sleep-related hypoventilation due to a medical disorder

"Sleep-Study Testing" is a diagnostic test that is used to diagnose sleep-related disorders by recording a person's brain waves, blood oxygen levels, heart rate and breathing during sleep. Two types of sleep-study tests are recognized in the diagnosis of sleep disordered breathing:

1. "Unattended (Home) Polysomnography (PSG)"/Home Sleep Apnea Test (HSAT) is a portable sleep study that can be done at home without the need for a technician on-site to monitor data.
2. "Attended (Facility or Laboratory) Nocturnal Polysomnography" is a test performed overnight in a sleep lab or facility that is administered and overseen by a technician.

"Apnea-Hypopnea Index (AHI)" is the number of apneas and hypopneas per hour of sleep recorded during a sleep study. The AHI is commonly used to determine the severity of sleep apnea. An apnea is defined by the cessation of airflow at the nose and mouth for a minimum of 10 seconds. A hypopnea is an abnormal respiratory event lasting ≥10 seconds with ≥ 30% reduction/signal excursion in

thoracoabdominal movement or airflow as compared to baseline, and with at least a ≥4% oxygen desaturation from pre-event baseline.

"Respiratory Disturbance Index (RDI)" is the number of apneas, hypopneas and respiratory effort-related arousals (RERAs) per hour of sleep recorded during a sleep study.

"Respiratory-Event Index (REI)" is a measurement of sleep disordered breathing on home sleep apnea testing defined as the number of apneas plus hypopneas during the sleep test divided by the total sleep or recording time reported in hours.

"Pulmonary Function Testing" is non-invasive testing that measures lung capacity, airflow and chest wall mechanics.

"Positive Airway Pressure Devices" are non-invasive equipment that assist in ventilation by delivering variable pressures of airflow during inspiration and expiration via an oral, nasal, or oronasal mask. They include:

1. Bi-level Positive Airway Pressure Devices (BPAP)
2. Continuous Positive Airway Pressure (CPAP)
3. Adaptive Servo-Ventilation devices (ASV)

Clinical Indications

Continuous Positive Airway Pressure (CPAP) / Bi-level Positive Airway Pressure Devices (BPAP - spontaneous mode, spontaneous/timed mode) / Adaptive Servo-Ventilation devices (ASV)

The Plan considers CPAP or BPAP devices provided by a network (durable medical equipment) DME provider (unless the member has out-of-network benefits) medically necessary if the following criteria are met:

1. Initiation of Therapy or Short-Term Therapy (up to 90 days)
    a. Prescription from treating licensed provider; *and*
    b. Meets the diagnostic and severity criteria for a sleep-related breathing disorder or other pulmonary disease as outlined:
        i. MCG criteria A-0431 for [Continuous Positive Airway Pressure (CPAP) Device] (HCPCS E0601); *or*
        ii. MCG criteria A-0337 for [CPAP Titration, Home Auto-titrating PAP (APAP)] (HCPCS E0601); *or*
        iii. MCG criteria A-0338 for [CPAP Titration, Sleep Center] (HCPCS E0601); *or*
        iv. MCG criteria A-0994 [Bilevel Positive Airway Pressure (BPAP) Device] for
            1. BPAP without a backup respiratory rate (HCPCS E0470); *or*
            2. BPAP with a back-up respiratory rate (HCPCS E0471, E0472); *or*
        v. Adaptive Servo-Ventilation devices (ASV) (e.g., BPAP Auto Servo-Ventilation) (HCPCS codes E0471) is considered medically necessary when ALL of the following criteria are met:

1. Member is diagnosed with complex sleep apnea, i.e., treatment-emergent central sleep apnea; *and*
2. Member does not have symptomatic chronic heart failure between Class II-IV in New York Heart Association (NYHA) Functional Classification*; and*
3. Cardiac assessment prior to initiation of treatment, member does not have left ventricular ejection fraction ≤45% and moderate to severe predominant central sleep apnea*; and*
4. Member has diagnostic polysomnography (PSG) that shows five or more predominantly obstructive respiratory events (obstructive or mixed apneas, hypopneas or respiratory effort related arousals [RERAs]) per hour of sleep; *and*
5. PSG during use of positive airway pressure (HCPCS code E0470) without a backup rate shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with both of the following:
    a. central apneas and central hypopneas ≥ 5/hour; *and*
    b. total number of central apneas and central hypopneas is >50% of total number of apneas and hypopneas.

2. Authorization for purchase for initial Long-Term Therapy (more than 90 days)
    a. Documented symptom and/or AHI/RDI/REI improvement with PAP therapy; *and*
    b. Documented follow up with prescribing provider within 90 days of initiation; *and*
    c. Documented compliance with use of PAP device, defined as usage on at least 70% of nights for an average of 4 hours per 24-hour period during a period of 30 consecutive days during the first 90 days after initiation.
3. Replacement device
    a. Device is consistently used on at least 70% of nights for an average of 4 hours per 24-hour period; *and*
    b. Device is not functioning appropriately; *and*
    c. Device has been evaluated by the supplying DME provider and has been deemed unable to be repaired; *and*
    d. The device is no longer covered under the manufacturer's warranty.

    Note:

    e. Replacement due to misuse or abuse is NOT covered.
    f. Duplicate equipment for traveling is NOT medically necessary and considered a convenience item.

Home Ventilators

For home ventilators that perform noninvasive ventilation (e.g., E0466,E0467), please see MCG criteria.

PAP Treatment Supplies

The Plan considers the following PAP treatment supplies medically necessary when ALL of the following are met:

1. They are provided by an in-network DME provider (unless the member has out-of-network benefits); *and*
2. Ordered via signed prescription by licensed treating practitioners dated within one year of request; *and*
3. Either a CPAP or BiPAP device has been approved based on the criteria above.

Masks

The Plan considers ONE of the four mask types below medically necessary for a given member. In cases where a member is unable to tolerate the initially provided mask type, eligibility for an alternative mask type will be considered provided documentation is submitted supporting the member is compliant with the PAP device, but unable to tolerate the mask type.

- Combination oral/nasal mask (A7027) - 1 per 3 months
    - Oral cushion used with combination oral/nasal mask (A7028) - 2 per month
    - Nasal pillows used with combination oral/nasal mask (A7029) - 2 per month
- Full face mask (A7030) - 1 per 3 months
    - Full face mask interface replacement (A7031)- 2 per month
- Nasal interface (mask or cannula type) (A7034) - 1 per 3 months
    - Cushion for nasal mask interface (A7032) - 2 per month
    - Nasal pillow for nasal cannula interface (A7033) - 2 per month
- Oral interface (A7044) - 1 per 6 months

Tubing

The Plan considers ONE of the following tubing types below medically necessary for a given member:

- Tubing with integrated heating element (A4604) - 1 per 3 months
- Tubing used with PAP devices (A7037) - 1 per 3 months

Filters

The Plan considers any ONE of the following filter types below medically necessary for a given member:

- Disposable filter (A7038) - 2 per month
- Non-disposable filter (A7039) - 1 per 6 months

Heated (E0562) and Non-heated (E0561) Humidifiers

The Plan considers an initial request for a heated or non-heated humidifier as medically necessary when:

1. No previous humidifier has been provided for initial requests within the plan year.

The Plan considers a replacement request for a heated or non-heated humidifier medically necessary when ALL of the following are met:

1. The device is not operating properly; *and*

2. The device has been evaluated by the supplying DME provider and has been deemed unable to be repaired; *or*
3. The device is no longer covered under the manufacturer's warranty.

Other PAP Equipment

The Plan considers the following PAP equipment types medically necessary when any ONE of the following are met:

- Headgear (A7035) - 1 per 6 months
- Chinstrap (A7036) - 1 per 6 months
- Exhalation port with or without swivel (A7045, bundled with mask interfaces) - 1 per 6 months
- Water chamber for humidifier (A7046, bundled at the time of initial supply) - 1 per 6 months

Experimental or Investigational / Not Medically Necessary

The following items are considered comfort or convenience items, are available over-the-counter, or are considered not medically necessary:

- Batteries, SD cards, modems, or other feature components for positive airway pressure devices
- DC adapters for positive airway pressure devices
- Electrical devices (e.g., Night Shift™ Sleep Positioner) as therapy for positional obstructive sleep apnea
- Electrosleep therapy
- Cleaning equipment for automatic or manual cleaning of interfaces, tubing, or other related supplies
- Duplicate equipment for traveling is not medically necessary and considered a convenience item.
- Non-PAP related home humidifiers
- Positive airway pressure bed pillows
- ProventTM Professional Sleep Apnea Therapy Device
- The treatment of snoring alone by any method is considered not medically necessary.
- Use of the miscellaneous durable medical equipment code (HCPCS code E1399)

Applicable Billing Codes (HCPCS/CPT Codes)

Codes considered medically necessary when clinical criteria are met:

Code	*Description*
94002	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day
94003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day

94004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
A4604	Tubing with integrated heating element for use with positive airway pressure device
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
A7030	Full face mask used with positive airway pressure device, each
A7031	Face mask interface, replacement for full face mask, each
A7032	Cushion for use on nasal mask interface, replacement only, each
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, non-disposable, used with positive airway pressure device
A7044	Oral interface used with positive airway pressure device, each
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each
E0466	Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions

E0470	Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous positive airway pressure (CPAP) device
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

Codes not considered medically necessary for indications listed in this Guideline:

Code	*Description*
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E1399	Durable medical equipment, miscellaneous ● Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: ● When this is billed for PAP cleaning machine, it is considered NOT medically necessary
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
95999	Unlisted neurological or neuromuscular diagnostic procedure ● Due to the broad nature of this code and lack of specificity in certain scenarios, clarification is provided below: ● When this is billed for PAP electrosleep therapy for OSA, it is considered NOT medically necessary

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