Current Effective Date: 12/29/24, 8/7/25
Status: Approved
Reviewed by Medical Policy Subcommittee: 9/9/21, 12/14/23, 12/29/24, 8/7/25
Reviewed Dates: 9/9/21, 12/14/24, 7/2/25

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DME Noninvasive Positive Pressure Ventilation Policy

Indication/Usage:

Noninvasive positive-pressure ventilation (NPPV) delivered by a nasal mask or facemask has gained increasingly widespread acceptance for the support of both chronic and acute respiratory failure. NPPV is being found to be a safe treatment and can reduce the need for intubation in some patients. The development of improved masks and ventilatory technology made this method of ventilation acceptable. This policy focuses on the use of the bi-level PAP ventilator, and is based on Medicare policy and on the conclusions of a consensus conference on noninvasive positive pressure ventilation (NAMDRC, 1999).

Per Durable Medical Equipment Medicare Administrative Carrier (DME MAC) policy, noninvasive positive pressure respiratory assistance provided by a respiratory assist device is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access (e.g., tracheostomy). It may be applied to

assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is to be distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of ventilatory support would lead to imminent demise of the patient

Definitions

1. Apnea is defined as the cessation of airflow for at least 10 seconds.

2. Apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. If the AHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a 2- hour period (i.e., greater than or equal to 10 events).

3. Central apnea-hypopnea index (CAHI) - For diagnosis of CSA, the central apnea central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device. For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared. If the CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).

4. Central Sleep Apnea is:

    - An AHI greater than 5; and
    - The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
    - A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
    - The presence of one or more of the following:
        - Sleepiness
        - Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
        - Awakening short of breath iv. Snoring v. Witnessed apneas; and There is no evidence of daytime or nocturnal hypoventilation.

5. Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or a bilevel PAP device without a backup rate feature when obstructive events have disappeared. These individuals have predominantly obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of

CPAP or bilevel PAP without a backup rate feature, they show a pattern of apneas and hypopneas that meets the definition of CSA described above.

Medical Indications for Authorization

Commercial and Medicare Members

SummaCare considers noninvasive positive pressure ventilation (NPPV) with bi-level positive airway pressure (bi-level PAP, BIPAP) devices or a bi-level PAP device with a backup rate feature medically necessary durable medical equipment (DME) for members who have restrictive thoracic/respiratory disorders, severe chronic obstructive pulmonary disease (COPD), central sleep apnea, or obstructive sleep apnea (bi-level PAP without backup rate feature only), and who meet the medical necessity criteria for these conditions:

1. Restrictive Thoracic Disorders:
   - COPD does not contribute significantly to the member's pulmonary limitation; *and*
   - Member has a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis, etc.) or a severe thoracic cage abnormality (e.g., post-thoracoplasty for tuberculosis, etc.), *and*
   - Member has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, cognitive dysfunction, etc., *and*
   - Member has clinically significant hypoxemia, as indicated by any of the following:
     - An arterial blood gas PaCO2, done while awake and breathing the member's usual FIO2 (fractional inspired oxygen concentration), is greater than or equal to 45 mm Hg; *or*
     - Sleep oximetry demonstrates oxygen saturation less than or equal to 88 % for at least 5 continuous minutes, done while breathing the member's usual FIO2; *or*
     - For progressive neuromuscular disease only, maximal inspiratory pressures less than 60 cm H20 or forced vital capacity (FVC) less than 50 % predicted.

2. Severe Chronic Obstructive Pulmonary Disease:
   - Member has symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), such as daytime hypersomnolenc, excessive fatigue, dyspnea, morning headache, cognitive dysfunction, etc.; *and*
   - Member has severe COPD, as indicated by either of the following:
     - An arterial blood gas PaCO2, done while awake and breathing the member's usual FIO2, is greater than or equal to 55 mm Hg; *or*

   - An arterial blood gas PaCO2 of 50 to 54 mm Hg and either of the following:

- Sleep oximetry demonstrates oxygen saturation less than or equal to 88 % for at least 5 continuous minutes for a minimum of 2 hours, done while breathing oxygen at 2 liters per minute (LPM) or the member's usual FIO2, whichever is higher, *or*
- Hospitalization related to recurrent (greater than or equal to 2 in a 12month period) episodes of hypercapnic respiratory failure; *and*
- Prior to initiating therapy, obstructive sleep apnea (OSA) (and treatment with continuous positive airway pressure (CPAP)) has been considered and ruled out. If all of the above criteria for members with COPD are met, a bilevel PAP device without a backup rate feature will be considered medically necessary. A bi-level PAP device with a backup rate feature will only be considered medically necessary for COPD if the member continues to meet the criteria, despite at least 2 months of compliant use (an average of 4 hours use per 24-hour period) of a bi-level PAP device without a backup rate feature.

3. Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA) : Prior to initiating therapy, a complete inpatient, attended polysomnogram must be performed documenting the following:
   - The diagnosis of CSA or CompSA (see Definitions); *and*
   - The ruling out of CPAP as effective therapy if either OSA or CSA is a component of the initially observed sleep-associated hypoventilation; *and*
   - Significant improvement of the sleep-associated hypoventilation with the use of NPPV device on the settings that will be prescribed for initial use at home, while breathing the member's usual FIO2.

4. Obstructive Sleep Apnea:
   - Member meets the criteria for CPAP, *and*
   - CPAP has been tried and proven ineffective or is not tolerated.

   If *all* of the above criteria are met, a bilevel PAP device without a backup rate feature will be considered medically necessary for members with OSA. A backup rate feature for a bilevel PAP device is of no proven value for the primary diagnosis of OSA and therefore will be considered experimental and investigational.

5. Tracheomalacia
   SummaCare considers continuous positive airway pressure medically necessary for the treatment of tracheomalacia.

6. Respiratory Failure Following_Surgery
   SummaCare considers NPPV medically necessary for postoperative hypoxemic respiratory failure that is intractable to or not appropriate for oxygen

   - Either a heated or non-heated humidifier is considered medically necessary.

- A liner used in conjunction with a PAP mask is considered a comfort/convenience item.

- Members should be re-evaluated after 2 to 3 months to evaluate their continued medical necessity for NPPV. For continued medical necessity after 3 months, the medical records should document that the member has been compliantly using the device (an average of 4 hours per 24-hour period), and that the member is benefiting from its use.

There are currently no NCD or LCD for NPPV per CMS, in the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Limitations

SummaCare considers NPPV experimental and investigational for all other indications (e.g., acute lung injury, asthma, pneumonia; as an alternative to endotracheal intubation following esophagectomy, bronchiolitis in infants and children, prevention of complications after pulmonary resection for lung cancer; not an all-inclusive list) because of insufficient evidence in the peer reviewed literature

HCPCS Codes

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 - A7039 Full face mask, each, face mask interface replacement, each, replacement cushion for nasal application, each, replacement pillows, pair, nasal interface (mask or cannula type), with or without headstrap, headgear, chinstrap, tubing. filter, disposable or filter nondisposable, 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
A7046 Water chamber for humidifier, used with positive airway pressure device, replacement, each
E0465 Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube)
E0466 Home ventilator, any type, used with non-hypheninvasive interface, (e.g., mask, chest shell)
E0467 Home ventilator, multi-hyphenfunction 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 FDA Ventilators
E0470 Respiratory assist device, bi-hyphenlevel pressure capability, without backup rate feature, used with non-hypheninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471 Respiratory assist device, bi-hyphenlevel pressure capability, with back-hyphenup rate feature, used with noninvasive interface, e.g., nasal or facial mask
E0561 Humidifier, non-hyphenheated, used with positive airway pressure device
E0562 Humidifier, heated, used with positive airway pressure device

Coverage Decisions

Coverage decisions made per CMS, Hayes and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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