Clinical Policy Title: Noninvasive positive pressure ventilation in adults

Clinical Policy Number: CCP.1126

Effective Date: January 1, 2015
Initial Review Date: July 18, 2014
Most Recent Review Date: August 7, 2018
Next Review Date: August 2019

Related policies:
CCP.1079 Treatment for obstructive sleep apnea in adults
CCP.1103 Home, domiciliary, and portable oxygen

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of noninvasive positive pressure ventilation to be clinically proven and, therefore, medically necessary when using bi-level positive airway pressure without a backup rate feature¹ for any of the following indications (Rochwerg, 2017):

- Acute hypercapnic respiratory failure (defined as pH ≤ 7.35, arterial partial pressure of carbon dioxide > 45 mmHg, and respiratory rate > 20 – 24 breaths per minute despite standard medical therapy) associated with either:
  - Acute cardiogenic pulmonary edema, excluding acute coronary syndrome or cardiogenic shock.
  - Chronic obstructive pulmonary disease exacerbation.

¹ Device delivers adjustable, variable levels of positive air pressure within a single respiratory cycle (InterQual®, 2017a).
• Acute post-operative hypoxemic respiratory failure (arterial partial pressure of oxygen < 60 mm Hg with a normal or low arterial partial pressure of carbon dioxide) in high-risk persons:
  – Immunocompromised members.
  – Abdominal or cardiothoracic surgery.
• Assistance in weaning from invasive mechanical ventilation for hypercapnic respiratory failure.
• Post-extubation prophylaxis for respiratory failure in members at high risk for re-intubation (e.g., patients > 65 years or those with underlying cardiac or respiratory disease).
• Palliation of dyspnea in members with terminal conditions.
• Members who decline invasive mechanical ventilation.
• Obstructive sleep apnea when the member meets criteria for continuous positive airway pressure (see CP# 07.01.01 [changed to CCP.1079] Treatment for obstructive sleep apnea in adults), but the treatment is ineffective or not tolerated (InterQual, 2017a).
• Central sleep apnea (primary or secondary) and all the following criteria (InterQual, 2017a; Aurora, 2012):
  – Documentation of central sleep apnea with a complete inpatient, attended polysomnogram.
  – Failure to respond to adequate trials of continuous positive airway pressure, adaptive servo ventilation, and oxygen therapies.
  – Member’s apnea-hypopnea index is normalized using bi-level positive airway pressure in a spontaneous timed mode.
  – Demonstration of significant improvement in sleep-associated hypoventilation using noninvasive positive pressure ventilation on the settings that will be prescribed for initial use at home, while breathing prescribed fractional inspired oxygen concentration.
• Hypoventilation syndrome and all of the following criteria (InterQual, 2017a):
  – Arterial partial pressure of carbon dioxide > 45 mm Hg while awake and breathing prescribed fractional inspired oxygen concentration.
  – Primary cause is not obstructive sleep apnea or central sleep apnea.
  – Forced expired volume (1 second)/forced vital capacity ratio ≥ 70 percent by spirometry.
  – Either physiologic criterion:
    ▪ Arterial partial pressure of carbon dioxide worsens by ≥ 7 mm Hg while sleeping or immediately upon waking and breathing prescribed fractional inspired oxygen concentration compared to initial blood gas results.
    ▪ Facility-based polysomnogram or home sleep test reveals oxygen saturation ≤ 88 percent for ≥ five continuous minutes while sleeping during ≥ a two-hour recording period, and desaturation is not caused by obstructive airway events.
• Stable, severe chronic obstructive pulmonary disease and all of the following criteria (InterQual, 2017a):
  – Obstructive sleep apnea and treatment with continuous positive airway pressure has been considered and ruled out. Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the member does not
suffer from some form of sleep apnea (obstructive sleep apnea, central sleep apnea, or complex sleep apnea) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation.

- Presence of symptoms of sleep-associated hypoventilation (nocturnal hypoxemia) such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, and cognitive dysfunction.
- Either physiologic criterion:
  - A PaCO$_2$ ≥ 52 mm Hg, observed while awake and breathing the member’s prescribed fractional inspired oxygen concentration.
  - Sleep oximetry demonstrates oxygen saturation ≤ 88 percent for at least five continuous minutes, done while breathing oxygen at two liters per minute or the member’s prescribed fractional inspired oxygen concentration, whichever is higher.

- Restrictive thoracic disorders (e.g., progressive neuromuscular conditions or severe chest wall deformity) and any of the following criteria (InterQual, 2017a; National Institute for Health and Care Excellence, 2016; Annane, 2014):
  - Symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), e.g., daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, or cognitive dysfunction.
  - Chronic obstructive pulmonary disease does not contribute significantly to the member’s pulmonary limitation.
  - Either physiologic criterion:
    - Arterial partial pressure of carbon dioxide ≥ 45 mm Hg, observed while awake and breathing prescribed fractional inspired oxygen concentration.
    - Nocturnal oximetry demonstrating oxygen saturation ≤ 88 percent for five total minutes while breathing prescribed fractional inspired oxygen concentration during ≥ two-hour recording period.
    - For progressive neuromuscular disease only, either maximal inspiratory pressure < 60 cm H$_2$O or forced vital capacity < 50 percent predicted.

Prestige Health Choice considers the use of bi-level positive airway pressure with a backup rate feature to be clinically proven and, therefore, medically necessary when all of the following criteria are met (InterQual, 2017b):

- Currently using bi-level positive airway pressure without a backup rate feature. Note: A member may be exempt from a prerequisite trial of a bi-level positive airway pressure without a backup rate feature at the medical reviewer’s discretion, if a backup rate feature is deemed medically necessary to prevent further respiratory decompensation.
- No improvement in, or a worsening of, the physiologic criteria established for bi-level positive airway pressure without a backup rate feature.

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$^2$ Device delivers variable levels of positive airway pressure using a timed backup feature that delivers pressure whenever an individual’s spontaneous breathing is insufficient (InterQual, 2017b).
• Demonstration of compliant use (an average of four hours’ use per 24-hour period) during the trial period.
• For any of the following indications:
  – Central sleep apnea (primary or secondary).
  – Hypoventilation syndrome (primary cause is not obstructive or central sleep apnea).
  – Restrictive thoracic disorders with no or mild chronic obstructive pulmonary disease by history or testing.
  – For severe chronic obstructive pulmonary disease only, if < 61 days of a trial of bi-level positive airway pressure without a backup rate feature, all criteria must be met:
    ▪ Arterial partial pressure of carbon dioxide worsens ≥ 7 mm Hg from baseline while awake and breathing the member’s prescribed fractional inspired oxygen concentration compared to blood gas results for initial trial of bi-level positive airway pressure.
    ▪ Sleep oximetry demonstrates oxygen saturation ≤ 88 percent for at least five continuous minutes, done while breathing oxygen at two liters per minute or the member’s prescribed fractional inspired oxygen concentration, whichever is higher.
    ▪ Desaturation not caused by obstructive airway events.
  – For severe chronic obstructive pulmonary disease only, if a trial of bi-level positive airway pressure without a backup rate feature is ≥ 61 days of compliant use, both criteria must be met:
    ▪ Arterial partial pressure of carbon dioxide remains ≥ 52 mm Hg while awake and breathing the member’s prescribed fractional inspired oxygen concentration.
    ▪ Sleep oximetry demonstrates oxygen saturation ≤ 88 percent for at least five cumulative minutes of nocturnal recording time (at least two hours), done while breathing oxygen at 2 liters per minute or the member’s prescribed fractional inspired oxygen concentration (whichever is higher).

For Medicare members only:

Prestige Health Choice considers the use of bi-level positive airway pressure with and without a backup feature to be clinically proven and, therefore, medically necessary when members meet the medical necessity criteria set forth in the following regulatory documents:
• Decision Memo for Noninvasive Positive Pressure Respiratory Assist Devices for Chronic Obstructive Pulmonary Disease (CAG-00052N).
• National Coverage Determination 280.1 Durable Medical Equipment Reference List.
• National Policy Article A52517 Respiratory Assist Devices.

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of noninvasive positive pressure ventilation are not medically necessary.

Contraindications to noninvasive positive pressure ventilation include, but are not limited to:

- Require invasive mechanical ventilation.
- Non-cooperation (e.g., agitation, belligerence, claustrophobia, or comatose).
- Hemodynamic instability.
- Nausea or vomiting.
- Gastrointestinal bleeding.
- Lacking an intact protective airway reflex.
- Problems with retained secretions.
- Facial trauma or surgery.
- Tracheostomy.

Noninvasive positive pressure ventilation should be applied by a trained and experienced team. Considerations that may limit application include staff learning curve and time requirements (nursing and respiratory therapy), as well as the potential for delay in definitive therapy (limit trials of therapy).

A three-month trial using noninvasive positive pressure ventilation is considered medically necessary to allow for proper adjustments of the device’s settings and member accommodation to its use and to evaluate member compliance and benefits (InterQual, 2017a and b). Ongoing treatment begins once the initial trial period has completed.

Members should be re-evaluated after at least 61 days (or earlier if medically indicated) of the initial trial to evaluate the continued medical necessity of noninvasive positive pressure ventilation. The medical records should document that the member has been compliant using the device (an average of four hours per 24-hour period) and is benefiting from its use (InterQual, 2017a and b).

Either a heated or non-heated humidifier is considered medically necessary for use with noninvasive positive pressure ventilation. Proper humidification may aid in comfort and improve utilization.

Bi-level positive airway pressure with a backup rate feature for treatment of obstructive sleep apnea is not medically necessary due to insufficient evidence of effectiveness for this indication.

Replacement of equipment is medically necessary when both criteria are met:

- Documentation of proper use and continued benefit.
- Either:
  - Equipment has been used for at least five years.
  - Equipment has been lost, stolen, or irreparably damaged.
This policy excludes the use of continuous positive airway pressure, noninvasive ventilation in pediatric populations, and noninvasive negative pressure ventilation.

Alternative covered services:

- Continuous positive airway pressure.
- Adaptive servo ventilation.
- Oxygen therapy.
- Tracheal intubation with mechanical ventilation.

Background

Respiratory failure is the inability of the respiratory system to perform one or both of its gas exchange functions: oxygenation and ventilation (carbon dioxide elimination). It is classified as either hypoxemic (type 1) or hypercapnic (type 2), and acute, chronic, or acute-on-chronic (American Thoracic Society, 2010).

The workup of patients in whom respiratory failure is suspected typically focuses on the cause and severity (American Thoracic Society, 2010). Signs and symptoms of include shortness of breath, rapid breathing, air hunger, and, in severe cases, cyanosis, confusion, and sleepiness. However, very significant respiratory failure may be present without dramatic signs or symptoms. Arterial blood gas measurement is essential for diagnosis.

Treatment of respiratory failure involves improving gas exchange and treating the underlying cause of the failure (American Thoracic Society, 2010). Ventilatory support may be needed to improve gas exchange delivered either invasively with intubation or noninvasively with complete or partial control of the breathing cycle. Depending on severity, acute respiratory failure is usually treated in a controlled environment such as an intensive care unit, whereas chronic, stable respiratory failure can be treated at home or at a long-term care facility.

Noninvasive ventilation:

Noninvasive ventilation delivers mechanically assisted breaths without the need for intubation or surgery to a preset inspiratory pressure value or volume (Hess, 2013). It is associated with few of the nosocomial complications recognized with endotracheal intubation (Williams, 2012). Major complications of noninvasive ventilation such as pneumonia, barotrauma, and hemodynamic effects causing hypotension can be life-threatening and strongly correlate with the degree of pulmonary and cardiovascular involvement (Carron, 2013).

Two types of noninvasive ventilation are positive-pressure and negative-pressure. Noninvasive negative-pressure ventilation uses a device that encases the thoracic cage, creating subatmospheric, vacuum-like
pressure around the thorax. The chest wall passively expands and the diaphragm descends, thereby inflating the lungs. Exhalation occurs with passive recoil of the chest wall.

Noninvasive positive pressure ventilation has supplanted noninvasive negative-pressure ventilation as the dominant mode of delivery. It delivers a mixture of air and oxygen with positive pressure throughout the respiratory tree, using a variety of interfaces (face mask, nasal mask or plugs, or a helmet) and ventilatory modes (e.g., volume ventilation, pressure support, bi-level positive airway pressure, proportional-assist ventilation, or continuous positive airway pressure). Continuous positive airway pressure and bi-level positive airway pressure are the two most commonly used modes. Noninvasive devices may be dedicated solely to noninvasive ventilation or capable of providing support through an endotracheal tube or mask. Current models incorporate oxygen blenders for precise delivery of fractional inspired oxygen concentration (Williams, 2012; American Thoracic Society, 2010).

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on June 11, 2018. Search terms were: “noninvasive ventilation” (MeSH), “respiration, artificial/methods” (MeSH), “respiratory muscles/physiopathology” (MeSH), and the free text terms “cost-effectiveness,” “sleep apnea,” and “noninvasive positive pressure ventilation.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified 11 systematic reviews and meta-analyses and three cost-effectiveness analyses for this policy. Noninvasive positive pressure ventilation has demonstrated a survival benefit and improved morbidity for several clinical indications. The strongest evidence for its use is in patients with acute respiratory failure due to acute cardiogenic pulmonary edema and exacerbation of moderate to severe chronic obstructive pulmonary disease using bi-level positive airway pressure mode with or without backup.
(McCurdy, 2012; Williams, 2012). These conditions respond relatively quickly to treatment and represent the hypercapnic and hypoxemic conditions best suited for noninvasive positive pressure ventilation.

Other uses of noninvasive positive pressure ventilation supported by lower-quality evidence include:

- Facilitating early weaning from invasive mechanical ventilation, particularly for persons with underlying chronic obstructive pulmonary disease (Burns, 2014; Lin, 2014; Olper, 2013; McCurdy, 2012; Williams, 2012).
- Preventing recurrent post-extubation respiratory failure in those at high risk such as the immunocompromised after transplantation or after abdominal or lung-resection surgery (McCurdy, 2012).

Very low-quality evidence supports limited use of noninvasive positive pressure ventilation in a subset of patients with severe, stable chronic obstructive pulmonary disease, particularly those with pronounced daytime hypercapnia (Shi, 2013; Chronic Obstructive Pulmonary Disease Working Group, 2012), and in persons with sleep apnea syndromes after adequate trials of continuous positive airway pressure, adaptive servo ventilation, and oxygen therapies have failed (Aurora, 2012).

There is insufficient evidence to support noninvasive positive pressure ventilation:

- For patients with chronic obstructive pulmonary disease exacerbation who failed usual medical care, as the superiority of noninvasive positive pressure ventilation or invasive mechanical ventilation has not been demonstrated (McCurdy, 2012).
- As initial support for acute respiratory failure due to any other etiology or in patients with established post-extubation respiratory failure (McCurdy, 2012).
- For patients with cystic fibrosis, as the impact of noninvasive positive pressure ventilation on secretion clearance, pulmonary exacerbations, and disease progression remains unclear. Longer-term and larger randomized controlled trials are needed to confirm these findings (Moran, 2013 updated 2017).

Evidence-based guidelines have issued criteria to help identify candidates for noninvasive positive pressure ventilation (Keenan, 2011; Celli, 2004):

- Patient cooperation (an essential component that excludes agitated, belligerent, or comatose patients).
- Dyspnea (moderate to severe, but short of respiratory failure).
- Tachypnea (> 24 breaths per minute).
- Increased work of breathing (accessory muscle use, pursed-lips breathing).
- Hypercapnic (uncompensated) respiratory acidosis (pH range 7.10 – 7.35).
- Hypoxemia (arterial partial pressure of oxygen/fractional inspired oxygen concentration < 200 mm Hg, best in rapidly reversible causes of hypoxemia).
Absolute contraindications to noninvasive positive pressure ventilation include any condition requiring immediate intubation (McCurdy, 2012). Other contraindications include hemodynamic instability, gastrointestinal bleeding, an inadequate protective airway reflex, retained secretions, recent upper airway surgery, status epilepticus, and potential upper airway obstruction. Noninvasive positive pressure ventilation should not be used in patients suffering from claustrophobia or who cannot tolerate the device (Carron, 2013). Noninvasive positive pressure ventilation may involve a trial to select patients with conditions best suited for treatment.

Evidence-based guidelines recommend a trial of noninvasive positive pressure ventilation for all patients with neuromuscular disease who have symptoms of respiratory fatigue (orthopnea) associated with functional respiratory dysfunction (a drop in forced vital capacity/maximum inspiratory pressure) or symptoms of hypoventilation in the presence of hypercapnia or nocturnal oxygen desaturation (Farrero, 2013; National Institute for Health and Care Excellence, 2010):

- Presenting symptoms (such as fatigue, dyspnea, or morning headache).
- Physiologic criteria (one of the following):
  - Arterial partial pressure of carbon dioxide > 45 mm Hg.
  - Nocturnal oximetry demonstrating oxygen saturation ≤88 percent for five consecutive minutes.
  - For progressive neuromuscular disease, maximal inspiratory pressure of 60 cm H2O or forced vital capacity < 50 percent predicted.
- Noninvasive positive pressure ventilation should be continued only if symptomatic and/or physiologic improvements are achieved after a trial of therapy.
- Portable respirators designed for life support are recommended. A significant benefit can be observed in patients who use noninvasive positive pressure ventilation for longer than four hours. Noninvasive positive pressure ventilation may be needed during exacerbations requiring more time on ventilatory support for patients already on home noninvasive positive pressure ventilation (Farrero, 2013).
- When a patient is on more than 12 hours of ventilation, essential equipment should include two respirators and extra batteries and mouthpieces or masks without support on the nasal dorsum, either nasal or nasal-buccal, to prevent pressure sores. In this case, some patients use different ventilatory parameters depending on the interface selected (Farrero, 2013).
- In the event noninvasive positive pressure ventilation is not tolerated or contraindicated, some patients may be able to be treated with noninvasive negative pressure ventilation (Corrado, 2002).

Policy updates:

In 2015, Prestige Health Choice identified four new systematic reviews and meta-analyses relevant to this policy (Bajaj, 2015; Cabrini, 2015; Bundchen, 2014; Goodacre, 2014). Bajaj (2015) confirmed the improved effectiveness of noninvasive ventilation compared to conventional oxygen therapy when used after planned extubation in a medical intensive care unit population. There was insufficient evidence to conclude that noninvasive ventilation improved exercise tolerance in patients with heart failure (Bundchen, 2014).
Goodacre (2014) found low- to fair-quality evidence that pre-hospital continuous positive airway pressure, but not bi-level positive airway pressure, was effective in reducing mortality and intubation rates.

In 2016, we added three new systematic reviews and meta-analyses to this policy (Amado-Rodriguez, 2016; Peng, 2016; Faria, 2015). There was inconclusive evidence to support noninvasive ventilation as an initial ventilator strategy for the treatment of acute respiratory failure in patients with hematological disorders, although acute respiratory failure in this population is associated with high mortality (Amado-Rodriguez, 2016). Peng (2016) and Cabrini (2015) produced conflicting conclusions regarding the use of noninvasive ventilation to facilitate early extubation in persons treated for acute respiratory failure. A Cochrane review determined noninvasive positive pressure ventilation was more effective than oxygen alone for treating acute respiratory failure in persons following upper abdominal surgery based on low-quality evidence (Faria, 2015). These new findings would not change the conclusions of the initial policy. Therefore, no changes to the policy are warranted at this time.

In 2017, we identified two new systematic review and meta-analyses (Huang, 2017; Xu, 2017), two Cochrane review updates (Moran, 2017; Annane, 2014), and one evidence-based guideline from the American College of Chest Physicians and the American Thoracic Society (Ouellette, 2017). There is insufficient evidence to support initial or early noninvasive ventilation for treating acute respiratory failure in immunocompromised patients, or treating acute hypoxemic, non-hypercapnic respiratory failure unrelated to chronic obstructive pulmonary disease exacerbation, or acute cardiogenic pulmonary edema (Huang, 2017; Xu, 2017). In these populations, while the evidence suggests short-term benefits in mortality, intubation rates, and lengths of stay, the study populations and interventions were very heterogeneous. Higher-quality research is needed to identify the persons who are most likely to benefit and the long-term outcomes before wider clinical use.

Both Cochrane review updates added new information to their analyses, but their conclusions did not change (Moran, 2017; Annane, 2014). The American College of Chest Physicians and American Thoracic Society found moderate-quality evidence supporting noninvasive ventilation when used immediately post-extubation in persons at high risk of ventilator failure and who had been ventilated for at least 24 hours (Ouellette, 2017). Physicians may choose to avoid extubation to noninvasive ventilation in selected patients for patient-specific factors (e.g., the inability to receive ventilation through a mask or similar interface). These results do not change previous conclusions and no policy changes are warranted.

In 2018, we added one joint guideline from the European Respiratory Society and American Thoracic Society for noninvasive ventilation for acute respiratory failure across various etiologies (Rochwerg, 2017) and InterQual criteria (2017 a and b) for noninvasive airway assistive devices. These new guidance documents were added to the medical necessity criteria.

Policy ID changed from CP# 07.02.05 to CCP.1126.

**Summary of clinical evidence:**
<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td><strong>Huang (2017)</strong>&lt;br&gt;Early noninvasive ventilation in immunocompromised patients with acute respiratory failure of various origins</td>
<td><strong>Key points:</strong>&lt;br&gt;• Systematic review and meta-analysis of five randomized controlled trials (592 total patients) comparing noninvasive ventilation versus oxygen therapy alone.&lt;br&gt;• Overall quality: low to moderate with low or unclear risk of bias.&lt;br&gt;• Compared to oxygen therapy alone, early noninvasive ventilation significantly reduced (relative risk [RR], 95% confidence interval [CI]):&lt;br&gt;  - Short-term mortality (0.62, 0.40 to 0.97, ( P = .04 )), but not long-term mortality (0.92, 0.74 to 1.15, ( P = .46 )).&lt;br&gt;  - Intubation rate (0.52, 0.32 to 0.85, ( P = .01 )).&lt;br&gt;  - Length of intensive care unit stay (mean difference [MD] -1.71 days, 95% CI -2.98 to 1.44, ( P = 0.008 )).&lt;br&gt;• Further studies are needed to identify in which selected patients noninvasive ventilation could be more beneficial, before wider application.</td>
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<td><strong>Moran (2017; update of 2013)</strong>&lt;br&gt;Cochrane review&lt;br&gt;Noninvasive ventilation for cystic fibrosis</td>
<td><strong>Key points:</strong>&lt;br&gt;• Systematic review of 10 randomized controlled trials (191 total participants).&lt;br&gt;• Overall quality: low to moderate with variable risk of bias.&lt;br&gt;• Limited evidence mainly from single-treatment sessions with small numbers of patients suggests noninvasive ventilation may be a useful adjunct to other airway clearance techniques, particularly for those with difficulty expectorating.&lt;br&gt;• Noninvasive ventilation plus oxygen may improve gas exchange during sleep better than oxygen therapy alone in moderate-to-severe disease.&lt;br&gt;• Unclear effect of noninvasive ventilation on exercise, pulmonary exacerbations, and disease progression.&lt;br&gt;• Adequately powered, long-term randomized controlled trials are needed.</td>
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<td><strong>Ouellette (2017)</strong> for the American College of Chest Physicians/American Thoracic Society&lt;br&gt;Guideline: inspiratory pressure augmentation during spontaneous breathing trials, protocols minimizing sedation, and noninvasive ventilation immediately after extubation</td>
<td><strong>Key points:</strong>&lt;br&gt;• Strong recommendation for preventive noninvasive ventilation immediately post-extubation in high-risk patients, who were ventilated for ( &gt; 24 ) hours, to improve selected outcomes (moderate-quality evidence).&lt;br&gt;• Patients at high risk of extubation failure may include patients with hypercapnia, chronic obstructive pulmonary disease exacerbation, congestive heart failure, or other serious comorbidities.&lt;br&gt;• Physicians may choose to avoid extubation to noninvasive ventilation in selected patients for patient-specific factors (e.g., the inability to receive ventilation through a mask or similar interface).&lt;br&gt;• Noninvasive ventilation applied immediately post-extubation is best to maximize benefits.</td>
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<td><strong>Rochwerg (2017)</strong> for the European Respiratory Society and American Thoracic Society&lt;br&gt;Guideline: noninvasive ventilation for acute respiratory failure</td>
<td><strong>Key points:</strong>&lt;br&gt;• Strong recommendations for noninvasive ventilation: hypercapnia with chronic obstructive pulmonary disease exacerbation; cardiogenic pulmonary edema.&lt;br&gt;• Conditional recommendations for noninvasive ventilation: immunocompromised with early respiratory failure; post-operative patients; palliative care; trauma; post-extubation prophylaxis in high-risk patients (( &gt; 65 ) years of age, cardiac or pulmonary comorbidities); weaning in patients with hypercapnia.</td>
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• No recommendation made for acute asthma exacerbation, de novo respiratory failure, or pandemic viral illness. |
| Early extubation in patients with acute exacerbation of chronic obstructive pulmonary disease | **Key points:**  
• Systematic review and meta-analysis of 17 low- to moderate-quality randomized controlled trials (959 total participants).  
• Compared with continuous invasive ventilation, early extubation followed by noninvasive ventilation used when pulmonary infection is controlled significantly reduced mortality, ventilator-associated pneumonia, weaning failures, re-intubations, duration of invasive ventilation, total duration of mechanical ventilation, both intensive care unit and hospital length of stay, and hospital costs.  
• Marked uncertainty in findings due to absence of high-quality evidence and long-term outcomes. Well-designed and adequately powered randomized controlled trials are required. |
| Bajaj (2015) | • Systematic review of randomized controlled trials comparing noninvasive ventilation to conventional oxygen therapy after planned extubation in medical intensive care unit.  
• Compared to conventional oxygen therapy, noninvasive ventilation significantly decreased re-intubation rate in patients with chronic obstructive pulmonary disease (RR 0.33, 95% CI 0.16 to 0.69, I²=0) and at high risk for extubation failure (RR 0.47, 95% CI 0.32 to 0.70, I² = 0), but not in a mixed medical intensive care unit population (RR 0.66, 95% CI 0.25 to 1.73, I² = 68%).  
• Our study confirms the findings of previous reviews. |
| Annane (2014; update of 2007) | • Systematic review of 10 randomized controlled trials (173 total patients) of any mode of nocturnal mechanical ventilation; significant heterogeneity among trials.  
• Overall quality: low with unclear or high risk of bias.  
• Results favored nocturnal noninvasive mechanical ventilation for prolonging survival (RR 0.62, 95% CI 0.42 to 0.91, P value = 0.01; four trials), reducing unplanned hospitalizations (RR 0.25, 95% CI 0.08 to 0.82, P value = 0.02; two studies), and alleviating symptoms of chronic hypoventilation in the short term.  
• Except for motor neuron disease and Duchenne muscular dystrophy, for which the natural history supports the survival benefit of mechanical ventilation against no ventilation, further larger randomized controlled trials should assess the long-term benefit of different types and modes of nocturnal mechanical ventilation on quality of life, morbidity and mortality, and its cost-benefit ratio in neuromuscular and chest wall diseases. |
| Burns (2014) | • Systematic review of 16 randomized controlled trials and quasi-randomized controlled trials (994 total adults mostly with chronic obstructive pulmonary disease).  
• Compared to invasive weaning, noninvasive weaning resulted in greater reductions in:  
  - Mortality (RR 0.53, 95% CI 0.36 to 0.80);  
  - Weaning failures (RR 0.63, 95% CI 0.42 to 0.96). |
**Citation**

**Content, Methods, Recommendations**

- Ventilator-associated pneumonia (RR 0.25, 95% CI 0.15 to 0.43).
- Length of stay in the intensive care unit (MD -5.59 d, 95% CI -7.90 to -3.28) and in the hospital (MD -6.04 d, 95% CI -9.22 to -2.87).
- Total duration of mechanical ventilation (MD -5.64 d, 95% CI -9.50 to -1.77).
- Tracheostomy rates (RR 0.19, 95% CI 0.08 to 0.47).
- Reintubation (RR 0.65, 95% CI 0.44 to 0.97).

- Mortality benefits were significantly greater in trials enrolling patients with chronic obstructive pulmonary disease than in trials enrolling mixed patient populations (RR 0.36 [95% CI 0.24 to 0.56] versus RR 0.81 [95% CI 0.47 to 1.40]).

### Shi (2013)

**Stable chronic respiratory failure in chronic obstructive pulmonary disease**

**Key points:**

- Meta-analysis of 11 randomized controlled trials: eight parallel, three crossover designs. Overall low quality with high degree of bias.
- From parallel randomized controlled trials, noninvasive positive pressure ventilation had no effect on (odds ratio [OR] or standard mean difference [SMD], 95% CI):
  - 12- or 24-month mortality (OR 0.82, 0.48 to 1.41).
  - Forced expired volume in one second (SMD 0.20, -0.06 to 0.46).
  - Maximal inspiratory pressure (SMD 0.01, -0.28 to 0.29).
  - Six-minute walk distance (SMD 0.17, -0.16 to 0.50).
- Noninvasive positive pressure ventilation improved arterial partial pressure of carbon dioxide but not arterial partial pressure of oxygen in patients with hypercapnia, while neither improved in patients with hypoxia.
- Inconsistent effect on dyspnea and blood gases.

### Williams for the Agency for Healthcare Research and Quality (2012)

**Acute respiratory failure due to any etiology**

**Key points:**

- Systematic review of 71 articles (representing 69 randomized controlled trials) of noninvasive positive pressure ventilation versus supportive care or mechanical ventilation in adults with acute respiratory failure of any etiology.
- Strong evidence: For acute respiratory failure due to severe exacerbations of chronic obstructive pulmonary disease or acute cardiogenic pulmonary edema, noninvasive positive pressure ventilation plus supportive care reduced mortality and intubation rates versus supportive care alone.
- Continuous positive airway pressure and bi-level positive airway pressure for acute cardiogenic pulmonary edema show similar efficacy.
- Although additional studies are needed, current studies support noninvasive positive pressure ventilation for patients with acute respiratory failure postoperatively or who are immunocompromised.
- Weak evidence: For postoperative care or post-transplant, noninvasive positive pressure ventilation may facilitate weaning from invasive ventilation or prevent recurrent post-extubation respiratory failure in those at high risk.
- Limited evidence shows similar treatment effects across different settings and possibly less benefit in trials designed to replicate usual clinical practice.
- Need further studies in less rigorously studied populations (e.g., acute respiratory failure in the context of obesity hypoventilation syndrome, acute respiratory distress syndrome, asthma, or interstitial lung disease) and to understand the role of training and effectiveness when part of routine clinical care.

### Chronic Obstructive Pulmonary Disease Working

**Key points:**
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| Group (2012) for Health Quality Ontario Stable chronic respiratory failure in severe to very severe chronic obstructive pulmonary disease | - Systematic review of eight randomized controlled trials and two systematic reviews of noninvasive positive pressure ventilation versus usual medical care; five randomized controlled trials of nocturnal noninvasive positive pressure ventilation, three randomized controlled trials used noninvasive positive pressure ventilation; sleep apnea excluded. Very low to low quality.  
- In the short term, compared to usual medical care, noninvasive positive pressure ventilation improves oxygen and carbon dioxide gas exchange, and exercise tolerance measured using the six-minute walking test but not forced expiratory volume (one second).  
- Over the long-term studies, noninvasive positive pressure ventilation had no effect on mortality, lung function, exercise tolerance (using the six-minute walking test), oxygen gas exchange, or carbon dioxide gas exchange.  
- Qualitative assessment:  
  - Noninvasive positive pressure ventilation improves dyspnea based on reduced Borg score or Medical Research Council dyspnea score versus usual medical care, but not hospitalizations.  
  - Health-related quality of life could not be evaluated. |

References

Professional society guidelines/other:


**Peer-reviewed references:**


**Centers for Medicare & Medicaid Services National Coverage Determinations:**


280.1 Durable Medical Equipment Reference List. Centers for Medicare & Medicaid Services website. [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&SearchType=Advanced&Cov erageSelection=Both&NCSSelection=NCA%7cCAL%7cCDE%7cCDIR%7cMM%7cMEDC%7cMEDC%7cMCD&ArticleType=SAD%7cEd&PolicyType=Final&s=All&KeyWord=respiratory+failure&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAAAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&SearchType=Advanced&CoverageSelection=Both&NCSSelection=NCA%7cCAL%7cCDE%7cCDIR%7cMM%7cMEDC%7cMEDC%7cMCD&ArticleType=SAD%7cEd&PolicyType=Final&s=All&KeyWord=respiratory+failure&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAAAAAAA%3d%3d&). Accessed June 11, 2018.


**Local Coverage Determinations:**

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>94660</td>
<td>Bilevel positive airway pressure.</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>J96.00</td>
<td>Acute respiratory failure, unspecified whether with hypoxia or hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.01</td>
<td>Acute respiratory failure with hypoxia</td>
<td></td>
</tr>
<tr>
<td>J96.02</td>
<td>Acute respiratory failure with hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.90</td>
<td>Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.91</td>
<td>Respiratory failure, unspecified with hypoxia</td>
<td></td>
</tr>
<tr>
<td>J96.92</td>
<td>Respiratory failure, unspecified with hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.10</td>
<td>Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.11</td>
<td>Chronic respiratory failure with hypoxia</td>
<td></td>
</tr>
<tr>
<td>J96.12</td>
<td>Chronic respiratory failure with hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.20</td>
<td>Acute and chronic respiratory failure, unspecified whether with hypoxia or hypercapnia</td>
<td></td>
</tr>
<tr>
<td>J96.21</td>
<td>Acute and chronic respiratory failure with hypoxia</td>
<td></td>
</tr>
<tr>
<td>J96.22</td>
<td>Acute and chronic respiratory failure with hypercapnia</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0470</td>
<td>Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask</td>
<td></td>
</tr>
<tr>
<td>E0471</td>
<td>Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask</td>
<td></td>
</tr>
</tbody>
</table>