Clinical Policy Title: Noninvasive positive pressure ventilation in adults

Clinical Policy Number: 07.02.05

Effective Date: January 1, 2015
Initial Review Date: July 18, 2014
Most Recent Review Date: August 17, 2017
Next Review Date: August 2018

Policy contains:
- Bilevel positive airway pressure.
- Respiratory failure.

Related policies:
CP# 07.01.01  Treatment for obstructive sleep apnea in adults
CP# 07.02.04  Home, domiciliary, and portable oxygen

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’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 AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania’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. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of noninvasive positive pressure ventilation (NIPPV) to be clinically proven and, therefore, medically necessary when the following general and medical necessity criteria are met:

General criteria (all criteria must be met):
- Need for immediate intubation and mechanical ventilation has been excluded.
- Member is fully cooperative (an essential component that excludes agitated, belligerent, claustrophobic, or comatose patients).
- Member has no contraindications to noninvasive ventilation, including but not limited to any of the following:
  - Hemodynamic instability.
  - Gastrointestinal bleeding.
  - Lacking an intact protective airway reflex.
  - Problems with retained secretions.
  - Recent upper airway surgery.
NIPPV is delivered using a bilevel positive airway pressure (also called bilevel PAP and BPAP) mode with or without a backup rate feature, depending on the medical necessity criteria as listed below.

- All patients started on noninvasive ventilation are monitored closely for signs of ventilatory failure until stabilized, paying attention to vital signs and gas exchange, as well as tolerance, comfort, air leaks, and patient-ventilator interaction.

Medical necessity criteria (one of the following criteria must be met):

- As support for acute hypercapnic respiratory failure (RF) (arterial partial pressure of carbon dioxide [PaCO2] > 50 mm Hg) in persons with either:
  - Acute cardiogenic pulmonary edema (ACPE).
  - Chronic obstructive pulmonary disease (COPD).

- As support for acute hypoxemic RF (arterial partial pressure of oxygen [PaO2] < 60 mm Hg with a normal or low PaCO2 in high-risk persons) after either:
  - Transplantation in immunocompromised patients.
  - Abdominal or lung resection surgery.

- To facilitate weaning from invasive mechanical ventilation after early extubation.

- To prevent recurrent post-extubation RF in patients at high risk after either:
  - Transplantation in immunocompromised patients.
  - Abdominal or lung resection surgery.

- In individuals with stable, severe COPD when one of the following criteria is met:
  - Presence of symptoms of sleep-associated hypoventilation (nocturnal hypoxemia) such as daytime hypersomnolence, excessive fatigue, dyspnea, morning headache, and cognitive dysfunction.
  - Severe COPD indicated by either:
    - A PaCO2 ≥ 55 mm Hg, observed while awake and breathing the member’s usual fractional inspired oxygen concentration (FiO2).
    - A PaCO2 of 50 to 54 mm Hg and one of the following:
      - Sleep oximetry demonstrates oxygen saturation ≤ 88 percent for at least five continuous minutes, done while breathing oxygen at two liters per minute (LPM) or the member’s usual FiO2, whichever is higher.
      - Hospitalization related to recurrent episodes (≥ two hospitalizations in a 12-month period) of hypercapnic RF.
  - Obstructive sleep apnea (OSA) (and treatment with continuous positive airway pressure [CPAP]) has been considered and ruled out prior to initiating NIPPV.

Note: 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 bilevel PAP device with a backup rate feature will only be considered medically necessary for COPD if the member continues to
meet the criteria set forth in the first two criteria above despite at least two months of compliant use (an average of four hours’ use per 24-hour period) of a bilevel PAP device without a backup rate feature.

- Support for RF in persons with progressive neuromuscular conditions or severe chest wall deformities who meet all of the following criteria:
  - Presence of symptoms of sleep-associated hypoventilation (nocturnal hypoxemia), e.g., daytime hypersomniaence, excessive fatigue, dyspnea, morning headache, and cognitive dysfunction.
  - COPD does not contribute significantly to the member’s pulmonary limitation.
  - Physiologic criteria (one of the following):
    - A PaCO2 ≥ 45 mm Hg, observed while awake and breathing the member's usual FiO2.
    - Nocturnal oximetry demonstrating oxygen saturation ≤ 88 percent for five consecutive minutes while breathing the member's usual FiO2.
    - For progressive neuromuscular disease, maximal inspiratory pressure of 60 cm/H2O or forced vital capacity < 50 percent predicted.

- Support for central sleep apnea related to congestive heart failure when all the following conditions are met:
  - Prior to initiating support, a complete inpatient, attended polysomnogram must be performed documenting the diagnosis of central sleep apnea.
  - Failure to respond to adequate trials of CPAP, adaptive servo ventilation, and oxygen therapies.
  - Bilevel PAP in a spontaneous timed (ST) mode is used to normalize the apnea-hypopnea index (AHI).
  - Significant improvement of sleep-associated hypoventilation is demonstrated with the use of NIPPV device on the settings that will be prescribed for initial use at home, while breathing the member’s usual FiO2.

**Limitations:**

All other uses of NIPPV are not medically necessary.

NIPPV 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 potential for delay in definitive therapy (limit trials of therapy).

For patients with severe COPD with nocturnal hypoxemia, progressive neuromuscular diseases, chest wall deformities, or central sleep apnea, a 60-day trial using NIPPV is considered medically necessary to allow for proper adjustments of the device's settings and patient accommodation to its use and to evaluate patient compliance and benefits.
Members should be re-evaluated after 60 days to evaluate the continued medical necessity of NIPPV. For establishment of continued medical necessity, the medical records should document that the member has been compliantly using the device (an average of four hours per 24-hour period) and that the member is benefiting from its use.

Either a heated or non-heated humidifier is considered medically necessary for use with NIPPV.

This policy excludes NIPPV used in obstructive sleep apnea. See related policy 07.01.01 Treatment for obstructive sleep apnea in adults.

This policy excludes the use of CPAP, noninvasive ventilation in pediatric populations, and noninvasive negative pressure ventilation.

**Alternative covered services:**

- CPAP.
- Adaptive servo ventilation.
- Oxygen therapy.
- Tracheal intubation with mechanical ventilation.

**Background**

RF 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 (Soo Hoo, 2014). COPD, ACPE, and pneumonia are the most common diagnoses associated with acute RF (Walkey, 2013).

The workup of patients in whom RF is suspected typically involves examinations designed to assess the cause and severity of RF (Soo Hoo, 2014). Signs and symptoms of RF include shortness of breath, rapid breathing, air hunger, and, in severe cases, cyanosis, confusion, and sleepiness. However, very significant RF may be present without dramatic signs or symptoms. Arterial blood gas measurement is essential for diagnosing RF.

Treatment of RF involves improving gas exchange and treating the underlying cause of the failure. 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 (Soo Hoo, 2014). Depending on severity, acute RF is usually treated in a controlled environment such as an intensive care unit (ICU), whereas chronic, stable RF can be treated at home or at a long-term care facility (Celli, 2004).

**Non-invasive ventilation (NIV):**
NIV delivers mechanically-assisted breaths without the need for intubation or surgery to a preset inspiratory pressure value or volume (Soo Hoo, 2014). NIV is associated with few of the nosocomial complications recognized with endotracheal intubation (Agency for Healthcare Research and Quality [AHRQ], 2012). Major complications of NIV 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 NIV are positive-pressure and negative-pressure. Noninvasive negative-pressure ventilation (NINPV) 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 (Soo Hoo, 2014).

NIPPV has supplanted NINPV as the dominant mode of delivery. NIPPV delivers a mixture of air and oxygen with positive pressure throughout the respiratory tree. NIPPV can use a variety of interfaces (face mask, nasal mask or plugs, or a helmet) and ventilatory modes (e.g., volume ventilation, pressure support, BPAP, proportional-assist ventilation or CPAP). CPAP and BPAP 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 FiO₂ (Soo Hoo, 2014; AHRQ, 2012).

Absolute contraindications to NIPPV include any condition requiring immediate intubation (Soo Hoo, 2014). 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 (Soo Hoo, 2014). NIPPV should not be used in patients suffering from claustrophobia or who cannot tolerate the device (Carron, 2013). NIPPV may involve a trial to select patients with conditions best suited for treatment (Soo Hoo, 2014).

Searches

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- AHRQ Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on July 7, 2017. Search terms were: “noninvasive ventilation (MeSH),” “respiration, artificial/methods (MeSH),” “respiratory muscles/physiopathology (MeSH),” and 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. NIPPV has demonstrated a survival benefit and improved morbidity for several clinical indications. The strongest evidence for the use of NIPPV is in patients with acute RF due to ACPE and exacerbation of moderate to severe COPD using BPAP mode with or without backup (AHRQ, 2012; McCurdy, 2012). These conditions respond relatively quickly to treatment and represent the hypercapnic and hypoxemic conditions best suited for NIPPV.

Other uses of NIPPV supported by lower-quality evidence include:

- Facilitating early weaning from invasive mechanical ventilation, particularly for persons with underlying COPD (AHRQ, 2012; McCurdy, 2012; Olper, 2013; Burns, 2014; Lin, 2014).
- Preventing recurrent post-extubation RF 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 NIPPV in a subset of patients with severe, stable COPD, particularly those with pronounced daytime hypercapnia (COPD Working Group, 2012; Shi, 2013), and in persons with sleep apnea syndromes after adequate trials of CPAP, adaptive servo ventilation, and oxygen therapies have failed (Aurora, 2012).

There is insufficient evidence to support NIPPV:

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

Evidence-based guidelines have issued criteria to help identify candidates for NIPPV (Keenan, 2011; Celli, 2004; British Thoracic Society [BTS], 2002):

- Patient cooperation (an essential component that excludes agitated, belligerent or comatose patients).
• Dyspnea (moderate to severe, but short of RF).
• Tachypnea (> 24 breaths/min).
• Increased work of breathing (accessory muscle use, pursed-lips breathing).
• Hypercapnic (decompensated) respiratory acidosis (pH range 7.10-7.35).
• Hypoxemia (PaO₂/FIO₂ < 200 mm Hg, best in rapidly reversible causes of hypoxemia).

Evidence-based guidelines recommend offering a trial of NIPPV for all patients with neuromuscular disease who have symptoms of respiratory fatigue (orthopnea) associated with functional respiratory dysfunction (drop in forced vital capacity [FVC]/maximum inspiratory pressure [MIP]) or symptoms of hypoventilation in the presence of hypercapnia or nocturnal oxygen desaturation (Consensus Conference Report, 1999; National Institute for Health and Clinical Excellence [NICE], 2010; Farrero, 2013):

• Presenting symptoms (such as fatigue, dyspnea, morning headache, etc.).
• Physiologic criteria (one of the following):
  • \( \text{PaCO}_2 > 45 \text{ mm Hg.} \)
  • Nocturnal oximetry demonstrating oxygen saturation \( \leq 88 \text{ percent for five consecutive minutes.} \)
  • For progressive neuromuscular disease, maximal inspiratory pressure of 60 cm/H₂O or FVC < 50 percent predicted.
• NIPPV 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 NIPPV for longer than four hours. NIPPV may be needed during exacerbations requiring more time on ventilatory support for patients already on home NIPPV (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 NIPPV is not tolerated or contraindicated, some patients may be able to be treated with NINPV (Corrado, 2002).

Policy updates:

In 2015, AmeriHealth Caritas Pennsylvania identified four new systematic reviews and meta-analyses relevant to this policy (Cabrini, 2015; Bajaj, 2015; Goodacre, 2014; Bundchen, 2014). Bajaj (2015) confirmed the improved effectiveness of NIV compared to conventional oxygen therapy when used after planned extubation in a medical ICU population. There was insufficient evidence to conclude that NIV improved exercise tolerance in patients with heart failure (Bundchen, 2014). Goodacre (2014) found low to fair quality evidence that pre-hospital CPAP, but not BPAP, 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 NIV as an initial ventilator strategy for the treatment of acute RF in patients with hematological disorders, although acute RF in this population is associated with high mortality (Amado-Rodriguez, 2016). Peng (2016) and Cabrini (2015) produced conflicting conclusions regarding the use of NIV to facilitate early extubation in persons treated for acute RF. A Cochrane review determined NIPPV was more effective than oxygen alone for treating acute RF 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 (ACCP) and the American Thoracic Society (ATS) (Ouellette, 2017). There is insufficient evidence to support initial or early NIV for treating acute RF in immunocompromised patients, or treating acute hypoxemic, non-hypercapnic RF unrelated to COPD exacerbation or ACPE (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 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 ACCP and ATS found moderate quality evidence supporting NIV 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 NIV 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.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Early NIV in immunocompromised patients with acute RF of various origins</td>
<td>- Systematic review and meta-analysis of five RCTs (592 total patients) comparing NIV versus oxygen therapy alone.</td>
</tr>
<tr>
<td></td>
<td>- Overall quality: low-to-moderate with low risk of bias.</td>
</tr>
<tr>
<td></td>
<td>- Compared to oxygen therapy alone, early NIV significantly reduced short-term mortality (RR 0.62, 95% CI 0.40 to 0.97, p = 0.04), intubation rate (RR 0.52, 95% CI 0.32 to 0.85, p = 0.01), and shorter length of ICU stay (MD -1.71 days, 95% CI -2.98 to 1.44, p = 0.008), but not long-term mortality (RR 0.92, 95% CI 0.74 to 1.15, p = 0.46).</td>
</tr>
<tr>
<td></td>
<td>- Further studies are needed to identify in which selected patients NIV could be more beneficial, before wider application.</td>
</tr>
<tr>
<td>Moran (2017; update of 2013)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Cochrane review</td>
<td>- Systematic review of 10 RCTs (191 total participants).</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| NIV for cystic fibrosis                      | • Overall quality: low-to-moderate with variable risk of bias.  
• Limited evidence mainly from single-treatment sessions with small numbers of patients suggests NIV may be a useful adjunct to other airway clearance techniques, particularly for those with difficulty expectorating.  
• NIV plus oxygen may improve gas exchange during sleep better than oxygen therapy alone in moderate-to-severe disease.  
• Unclear effect of NIV on exercise, pulmonary exacerbations, and disease progression.  
• Adequately-powered, long-term RCTs are needed.                                                                                                                                                                                                                                               |
| Ouellette (2017) for the ACCP/ATS             | **Key points:**  
• Strong recommendation for preventive NIV immediately post-extubation in high-risk patients, who were ventilated for > 24 hours, to improve selected outcomes (moderate quality evidence).  
• Patients at high risk of extubation failure may include patients with hypercapnia, COPD, CHF, or other serious comorbidities.  
• Physicians may choose to avoid extubation to NIV in selected patients for patient-specific factors e.g., the inability to receive ventilation through a mask or similar interface. NIV applied immediately post-extubation is best to maximize benefits. |
| Xu (2017)                                     | **Key points:**  
• Systematic review and meta-analysis of 11 RCTs (1,480 total patients) comparing NIV to standard oxygen therapy.  
• Overall quality: moderate-to-high. Blinding not feasible.  
• NIV significantly reduced intubation rate (summary risk ratio [RR] 0.59 (95% CI, 0.44-0.79; p = 0.0004) and hospital mortality (RR 0.46; 95% CI, 0.24-0.87; p = 0.02).  
• Insufficient evidence to recommend BPAP, helmet, or face/nasal mask due to the limited number of trials available.  
• Large rigorous RCTs are needed.                                                                                                                                                                                                                                                     |
| Amado-Rodriguez (2016)                        | **Key points:**  
• Systematic review and meta-analysis of 13 studies of various types (2,380 total patients).  
• Meta-analyses that compensated for significant publication bias and heterogeneity showed a significant risk of death after NIV failure compared to initial intubation (relative risk [RR], 1.07; 95% confidence interval [CI], 1.00 to 1.14).  
• NIV failure may worsen the prognosis, mainly in less severe patients.                                                                                                                                                                                                                   |
| Peng (2016)                                   | **Key points:**  
• Systematic review and meta-analysis of 17 low- to moderate-quality RCTs (959 total participants).  
• Compared with continuous invasive ventilation, early extubation followed by NIV 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 (ICU) and hospital length of stay (LOS), and hospital costs.  
• Marked uncertainty in findings due to absence of high-quality evidence and long-term outcomes. Well-designed and adequately powered RCTs are required.                                                                                     |
<p>| Bajaj (2015)                                  | <strong>Key points:</strong>                                                                                                                                                                                                                                                                                                                                               |</p>
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| NIV after planned extubation | • Systematic review of RCTs comparing NIV to conventional oxygen therapy after planned extubation in medical ICU.  
• Compared to conventional oxygen therapy, NIV significantly decreased re-intubation rate in patients with COPD (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 ICU population (RR 0.66, 95% CI 0.25 to 1.73, I² = 68%).  
• Our study confirms the findings of previous reviews. |
| Cabrini (2015) Prevention or treatment of acute RF | **Key points:**  
• Systematic review and meta-analysis of 78 RCTs.  
• NIV reduced mortality (12.6% in the NIV group vs. 17.8% in control arm; RR = 0.73, 95% CI 0.66 to 0.81; p<0.001; 7,365 total patients) at the longest available follow-up.  
• Results suggest NIV reduced mortality when used to treat or prevent acute RF, but not to facilitate an earlier extubation.  
• Whenever NIV is indicated, an early adoption should be promoted. |
| Faria (2015) Cochrane review NIPPV for acute RF post-abdominal surgery | **Key points:**  
• Systematic review and meta-analysis of two RCTs or quasi-RCTs (269 total participants). Very low to low quality with high risk of bias.  
• Compared to oxygen therapy:  
  - CPAP or BPAP reduces tracheal intubation rate (RR 0.25; 95% CI 0.08 to 0.83) and ICU LOS (mean difference [MD] -1.84 days; 95% CI -3.53 to -0.15), but no difference in mortality or hospital LOS. Insufficient evidence for an effect on anastomotic leakage, pneumonia-related complications, and sepsis or infections.  
  - In one trial (60 participants), BPAP may improve blood gas levels and blood pH one hour after the intervention (PaO₂: MD 22.5 mm Hg; 95% CI 17.19 to 27.81; pH: MD 0.06; 95% CI 0.01 to 0.11; PaCO₂: MD -9.8 mm Hg; 95% CI -14.07 to -5.53).  
• No data provided on gastric insufflation, fistulae, pneumothorax, bleeding, skin breakdown, eye irritation, sinus congestion, oronasal drying, or patient-ventilator asynchrony.  
• More good-quality studies are needed to confirm these findings. |
| Annane (2014; update of 2007) Cochrane review Neuromuscular and chest wall disorders | **Key points:**  
• Systematic review of 10 RCTs (173 total patients) of any mode of nocturnal mechanical ventilation (NMV); significant heterogeneity among trials.  
• Overall quality: low with unclear or high risk of bias.  
• Results favored NMV 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 RCTs 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. |
<p>| Bundchen (2014) | <strong>Key points:</strong> |</p>
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Heart failure                  | • Systematic review of four low-quality RCTs.  
• A meta-analysis including 18 participants showed NIV prior to the six-minute walk test promoted increased distance (MD 65.29 m, 95% CI 38.80 to 91.78).  
• Results suggest NIV improves short-term exercise tolerance. High uncertainty in findings due to limited number of studies and participants. |
| Burns (2014)                   | **Key points:**  
• Systematic review of 16 RCTs and quasi-RCTs (994 total adults mostly with COPD).  
• Noninvasive weaning vs. invasive weaning reduced mortality (RR 0.53, 95% CI 0.36 to 0.80); weaning failures (RR 0.63, 95% CI 0.42 to 0.96); ventilator-associated pneumonia (RR 0.25, 95% CI 0.15 to 0.43); LOS in the ICU (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); and 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), and reintubation (RR 0.65, 95% CI 0.44 to 0.97).  
• Mortality benefits were significantly greater in trials enrolling patients with COPD than in trials enrolling mixed patient populations (RR 0.36 [95% CI 0.24 to 0.56] vs. RR 0.81 [95% CI 0.47 to 1.40]). |
| Cochrane review                | Post-extubation weaning                                                                                                                                                                                                             |
| Goodacre (2014)                | **Key points:**  
• Systematic review, network meta-analysis, and individual patient data meta-analysis of eight low- to fair-quality RCTs and two quasi-RCTs (six CPAP, four BPAP, sample sizes 23 to 207).  
• Compared to baseline care (ill-defined but often supplemental oxygen), pre-hospital CPAP can reduce mortality and intubation rates; the effectiveness of pre-hospital BPAP is uncertain.  
• Comparisons of pre-hospital CPAP to in-hospital NIV are lacking.  
• The network meta-analysis using individual patient-level data and aggregate data suggested that gender was a treatment effect modifier on mortality. |
| Lin (2014)                     | **Key points:**  
• Meta-analysis of 10 trials (1,382 total adults with COPD): NIV vs. standard medical therapy.  
• Immediate post-extubation with established RF (two trials): no change in reintubation rate (RR 1.02, 95% CI 0.83 to 1.25) and ICU mortality (RR 1.14, 95% CI 0.43 to 3.00).  
• Early application of NIV after extubation (n = 1080) also did not decrease the reintubation rate (RR 0.75, 95% CI 0.45 to 1.15) significantly.  
• Planned extubation (eight trials): significant reductions in the reintubation rate (RR 0.65, 95% CI 0.46 to 0.93), ICU mortality rate (RR 0.41, 95% CI 0.21 to 0.82) and hospital mortality rate (RR 0.59, 95% CI 0.38 to 0.93). |
| Chiumello (2013)               | **Key points:**  
• Systematic review and meta-analysis of 10 low-quality studies (368 total patients).  
• NIV vs. standard care (oxygen therapy and invasive mechanical ventilation): RR 0.26 (95% CI 0.09 to 0.71, p = 0.003).  
• CPAP vs. NIV: no advantage in mortality.  
• NIV significantly increased PaO2 and reduced intubation rate, the incidence of overall complications, and infections. |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olper (2013)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Post-extubation weaning | • Systematic review and meta-analysis of 14 RCTs (1,211 total patients undergoing cardiothoracic surgery).  
• NIV reduced the reintubation rate (RR 0.29; 95% CI, 0.16 to 0.53; P for efficacy < 0.0001; I² = 0), hospital LOS and mortality.  
• Benefits of NIV are more important in patients with ongoing acute RF (RR, 0.25; 95% CI, 0.07 to 0.89) and in those at high risk of developing postoperative pulmonary complications (RR, 0.19; 95% CI, 0.04 to 0.84).  
• Prophylactic use of NIV in patients at low risk showed no significant effect on reintubation rate (RR = 0.42; 95% CI, 0.12 to 1.48) or other outcomes considered except for oxygenation.  
• Large RCTs needed to confirm results. |
| Radunovic (2013) | **Key points:**                   |
| Cochrane review | • Systematic review of one RCT (41 total patients) of NIPPV vs. UMC; low risk of bias.  
• Higher median survival with NIPPV versus UMC: 219 days versus 171 days, estimated 95% CI 12 to 91 days, P = 0.0062.  
• NIPPV improves or maintains QoL in persons with ALS and improves sleep-related symptoms in some subgroups who have severe bulbar dysfunction.  
• NIV improved survival and some measures of QoL in subgroups with better bulbar function.  
• Author’s comments: It is unlikely there will be further RCTs of NIV in unselected cohorts of people with ALS. It would be unethical not to offer NIV to all people with ALS who have symptoms of nocturnal hypoventilation. Adverse effects were underreported. |
| Shi (2013)      | **Key points:**                   |
| Stable chronic RF in COPD | • Meta-analysis of 11 RCTs: eight parallel, three crossover designs. Overall low quality with high degree of bias.  
• From parallel RCTs, NIPPV had no effect on 12- or 24-month mortality (odds ratio [OR] 0.82, 95% CI 0.48 to 1.41), FEV₁ (standard mean difference [SMD] 0.20, 95% CI -0.06 to 0.46), maximal inspiratory pressure (SMD 0.01, 95% CI -0.28 to 0.29) or six-minute walk distance (SMD 0.17, 95% CI -0.16 to 0.50).  
• NIPPV improved PaCO₂: but not PaO₂: in patients with hypercapnia, while neither improved in patients with hypoxia.  
• Inconsistent effect on dyspnea and blood gases. |
| AHRQ (2012)     | **Key points:**                   |
| Acute RF due to any etiology | • Systematic review of 71 articles (representing 69 RCTs) of NIPPV vs. supportive care or mechanical ventilation in adults with acute RF of any etiology.  
• Strong evidence: For acute RF due to severe exacerbations of COPD or ACPE, NIPPV plus supportive care reduced mortality and intubation rates compared with supportive care alone.  
• BPAP studied more rigorously, but direct comparisons of CPAP and BPAP for ACPE show similar efficacy.  
• Although additional studies are needed, current studies support NIPPV for patients with acute RF postoperatively or who are immunocompromised. |
### Citation

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD Working Group (2012)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Stable chronic RF in severe to very severe COPD | • Systematic review of eight RCTs and two systematic reviews of NIPPV vs. UMC; five RCTs used nocturnal NIPPV, three RCTs used diurnal NIPPV largely in closely supervised environment; sleep apnea excluded. Very low to low quality.  
• In the short term, NIPPV improves ventilation on oxygen gas exchange, CO₂ gas exchange, and exercise tolerance measured using the six-minute walking test but not FEV₁ vs. UMC.  
• Over the long-term studies, no effect of NIPPV on mortality, lung function (FEV₁), exercise tolerance using the six-minute walking test, oxygen gas exchange, or CO₂ gas exchange.  
• Qualitative assessment:  
  - NIPPV improves dyspnea based on reduced Borg score or Medical Research Council dyspnea score versus UMC but not hospitalizations.  
  - Health-related quality of life could not be evaluated. |
| McCurdy (2012) | **Key points:** |
| Acute RF in COPD | • Systematic review of multiple RCTs of very low to moderate quality.  
• For first-line treatment of acute RF (11 RCTs, 1,000 total patients), NIPPV + UMC had significantly lower intubation rates, in-hospital mortality, mean LOS, and complication rates than UMC alone.  
• NIPPV vs. invasive mechanical ventilation (IMV) after failed UMC (two RCTs, n = 205), insufficient evidence to draw conclusions  
• Compared to weaning with IMV (two RCTs, n = 80.), NIPPV significantly reduced mortality, nosocomial pneumonia, and weaning failure, but had non-significant reductions in mean LOS and mean duration of mechanical ventilation.  
• Post-extubation from IMV, insufficient evidence to draw conclusions. |

### References

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**


280.1 Durable Medical Equipment Reference List. CMS website. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&SearchType=Advanced&C覆盖Selection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SA%7cEd&PolicyType=Final&s=All&KeyWord=respiratory+failure&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAAABAAAAA%3d&. Accessed July 10, 2017.

**Local Coverage Determinations (LCDs):**


**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>
</tr>
</tbody>
</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>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>