DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Noninvasive positive pressure ventilation (NIPPV) is the use of assisted ventilation without an artificial airway (e.g., tracheostomy tube or endotracheal tube) that is applied as positive pressure to the airway opening. The use of NIPPV has increased in the acute care hospital setting, the long-term care hospital and the home for the management of patients with chronic respiratory failure requiring prolonged mechanical ventilation. Home NIPPV has been investigated for use in patients with obstructive lung disease, neuromuscular disease, obesity hypoventilation syndrome (OHS), and restrictive chest wall disease.

The FDA has approved several portable home ventilators (e.g. Trilogy™, Newport®, Vela®, IVent, Puritan™, and LTV®) to provide continuous or intermittent positive pressure ventilation through invasive or non-invasive interface for use in those individuals who require mechanical ventilation. On February 11, 2014 Phillips Respironics initiated a voluntary recall to address a potentially defective component on Trilogy Ventilators Models 100, 200, and 202. ⁴⁰⁻⁴¹

This policy does not address the use of other respiratory assist devices including BiPAP or CPAP.

RECOMMENDATION ³⁻⁹⁻¹⁰⁻³¹

Home use of a non-invasive positive pressure ventilator used with noninvasive interface, (e.g., mask, chest shell) for the treatment of chronic respiratory failure is considered medically necessary when ALL of the following criteria are met:

- Diagnosis of chronic respiratory failure due to progressive neuromuscular disease (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord diseases, diaphragmatic paralysis, myasthenia gravis, amyotrophic lateral sclerosis); and
- Diagnosis and prescription for the device must be made by a physician specialist in the disease or a pulmonologist; and
Device is FDA approved for the clinical indications; and

Mechanical ventilation required due to respiratory insufficiency with ANY ONE of the following:
  - Arterial O2 saturation < 88% for 5 consecutive minutes during nocturnal oximetry; or
  - Arterial PCO2 ≥ 45 mm Hg (6.0 kPa), or
  - Maximal inspiratory pressures < 60 cm/H2O or
  - Forced Vital Capacity (FVC) < 50% predicted

None of the following conditions are present:
  - alteration in level of consciousness (i.e. alert and oriented)
  - anatomic abnormality that precludes mask fitting (facial or neurological surgery, trauma, or deformity)
  - high risk for aspiration (excessive secretions, impaired cough or inability of mechanically assisted cough to clear secretions)
  - swallowing disorder
  - inability to cooperate/protect airway
  - upper airway obstruction

**Coverage Exclusions 3-9 -10-31-38**

Home non-invasive positive pressure ventilators are excluded for ALL of the following conditions:

- For the treatment of obstructive sleep apnea as the clinical outcomes have not been shown to be superior to other standard treatments (e.g., CPAP, BiPAP); and
- For the treatment of other conditions/diseases including but not limited to chronic obstructive pulmonary disease (COPD) and cystic fibrosis due to insufficient evidence in the peer reviewed medical publications

**Summary of Medical Evidence 10-37**

The peer reviewed published literature is sufficient to confirm improved outcomes of NIPPV in patients with progressive neuromuscular disease (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord diseases, diaphragmatic paralysis, myasthenia gravis, amyotrophic lateral sclerosis). There are meta-analysis, systematic reviews and randomised controlled trials that have determined positive clinical effects of non-invasive ventilation and validate clinical net health outcomes of home NIPPV.

The peer reviewed published medical literature is insufficient to confirm improved outcomes of NIPPV in patients with chronic COPD, cystic fibrosis and obstructive sleep apnea. Further investigation is needed with larger populations to determine appropriate candidates for NIPPV and validate long-term, predictable outcomes. Studies thus far have yielded mixed results due to methodological issues and problems with compliance. There is a need for long-term randomised controlled trials which are adequately designed to determine the clinical effects of non-invasive ventilation and explore potential interventions that can improve compliance, decrease adverse events associated with non-compliance, and validate clinical net health outcomes of home NIPPV. A recent Cochrane (Struik et al. 2013) review concludes that nocturnal-NIPPV at home for at least three months in hypercapnic patients with stable COPD had no consistent clinically or statistically significant effect on gas exchange, exercise tolerance, HRQoL, lung function, respiratory muscle strength or sleep efficiency. 26 Meta-analysis of the two new long-term studies did not show significant improvements in blood gases, HRQoL or lung function after 12 months of NIPPV. 24-26 In a small RCT, Murphy et al (2017) investigated the effect of home NIV plus oxygen on time to readmission or death in patients with persistent hypercapnia after an acute COPD exacerbation. 116 patients who received NIV during a COPD exacerbation and had persistent hypercapnia (PaCO2 >53 mmHg) were assigned to nocturnal NIV or supplemental oxygen after discharge. Nocturnal NIV prolonged the median time to readmission or death compared with supplemental oxygen alone (4.3 versus 1.4 months, respectively).
One reason for the success of NIV in this study may be the use of high inspiratory pressures (median 24 cm H2O) titrated to reduce transcutaneous carbon dioxide by ≥4 mmHg. However, the small sample sizes of these studies preclude a definite conclusion regarding the effects of NIPPV in COPD.

The 2016 Guideline entitled “Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) indicates that Non-invasive ventilation (NIV) is increasingly used in patients with stable very severe COPD. Randomized controlled trials provide contradictory results regarding the clinical benefits of long-term NIV in patients with COPD and chronic hypercapnia, especially in terms of health status and survival. Thus, there is insufficient evidence to formulate recommendations. The combination of NIV with long-term oxygen therapy may be of some use in a selected subset of patients, particularly in those with pronounced daytime hypercapnia. It may improve survival but does not improve quality of life. However, in patients with both COPD and obstructive sleep apnea there are clear benefits from continuous positive airway pressure (CPAP) in both survival and risk of hospital admission. The 2017 GOLD Guidelines indicate that NIV may improve hospitalization-free survival in select patients after recent hospitalization, particularly in those with pronounced daytime hypercapnia (PaCO2 ≥ 52 mmHg). Some trials show improvement and others show no improvement and conclude that there is conflicting evidence whether NIPPV improves survival in COPD.

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<td>J96.10 – J96.12</td>
<td>Chronic respiratory failure</td>
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**REFERENCES**

**Government Agency**


**Professional Society Guidelines**


6. Global Strategy for the Diagnosis, Management and Prevention of COPD:


Peer Reviewed Publications


Other Resources
39. UpToDate:
   • Hill NS, Kramer NR. Practical aspects of nocturnal noninvasive ventilation in neuromuscular and chest wall disease. 2017
   • Hill NS, Kramer NR Types of noninvasive nocturnal ventilatory support in neuromuscular and chest wall disease. 2017
   • Gay P. Nocturnal ventilatory support in COPD. 2017.

Peer Review: Policy reviewed by AMR practicing physician board certified in Internal Medicine, Pulmonary Disease.
10/10/17

Revision History: 12/17: The clinical criteria have not changed. References and professional society guidelines were updated.