Molina Clinical Policy
Noninvasive Positive Pressure Ventilation: Policy No. 275

Last Approval: 12/13/2023
Next Review Due By: December 2024

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This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Non-invasive positive pressure ventilation (NIPPV) refers to the delivery of mechanical positive pressure ventilatory support via a non-invasive interface (nasal mask, partial- or full-face mask, or nasal pillows), as opposed to an invasive interface (endotracheal tube or tracheostomy tube). 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 both acute respiratory failure and chronic respiratory failure requiring prolonged mechanical ventilation. Home NIPPV has mainly been investigated for use in patients with obstructive lung disease, neuromuscular disease, obesity hypoventilation syndrome (OHS), and restrictive chest wall disease (Bach 2023; Gay 2023; [1-2]Hill & Kramer 2022; Martin 2022).

Both bilevel positive airway pressure (BPAP) devices and non-invasive ventilators can deliver NIPPV. However, their technical features may vary considerably. Key areas of variability include the mode of ventilation (pressure targeted versus volume targeted), monitoring capabilities, safety and alarm systems, and the presence of a flow sensor. Due to advancements in technology, it has become increasingly more difficult to clearly discern one device category from the other. Many home ventilators are multi-mode ventilators, capable of providing multiple modes of ventilation, including pressure control, volume control, assist/control, synchronized intermittent mandatory ventilation, (BPAP, or continuous positive airway pressure (CPAP) and are capable of supporting patients invasively or non-invasively (Hyzy & Jia 2023).

Newer modes of NIPPV available on certain models of non-invasive ventilators include average volume-assured pressure support (AVAPS), average volume-assured pressure support auto-titrating expiratory positive airway pressure (AVAPS-AE), and intelligent volume-assured pressure support (iVAPS). AVAPS and iVAPS are the same mode of ventilation with the difference being trademarking of names: AVAPS is trademarked to Philips Respironics and iVAPS is trademarked to ResMed. AVAPS and iVAPS allow the clinician to set a target tidal volume, minimum and maximum inspiratory positive airway pressure, a backup respiratory rate, and an expiratory positive airway pressure. Each device has a specific algorithm that monitors the average achieved tidal volume, usually over the last rolling minute, and adjusts the inspiratory pressure in small increments in order to achieve the targeted tidal volume. The targeted tidal volume is typically achieved several minutes after initiation of therapy as it takes time for the device to “ramp up” to the patient’s needs. AVAPS-AE functions similar to AVAPS and iVAPS with the addition of allowing the clinician to set a minimum and maximum expiratory pressure. The expiratory pressure will increase or decrease based on the device-specific algorithm and patient-specific needs as determined by the algorithm (Yarrarapu et al. 2023).

Considering the user’s needs when selecting an appropriate positive pressure ventilation assist device is essential. For situations in which there is a risk of acute respiratory failure, hypoventilation, or apnea, the non-invasive ventilator will sound an alarm where the home BPAP unit may not. Non-invasive ventilators are also generally equipped with batteries to serve as a back-up source of power for several hours should the primary power source fail. Additionally, non-invasive ventilators have the capability of delivering ventilation based on volume and precise levels of oxygen needed by more complex patients (Hyzy & Jia 2023; Yarrarapu et al. 2023).

Regulatory Status

Multiple ventilators are available for NIPPV use within a facility (acute care hospital or long-term care facility) or the

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home setting. Certain ventilators have FDA-approval for use within both settings. Ventilators approved for continuous use within a facility may be found in the FDA 510(k) database by searching product code "CBK." Ventilators approved for home use may be found by using the subsequent product code "NOU."

COVERAGE POLICY

This policy does not address the use of other respiratory assist devices including bilevel positive airway pressure (BPAP) or continuous positive airway pressure (CPAP) devices. Please see Milliman MCG for criteria for BPAP and CPAP devices. These devices are considered first line treatment for many conditions and should be tried before following the criteria outlined below whenever appropriate.

Non-invasive positive pressure ventilation (NIPPV) with a ventilator approved by the FDA for home use **may be considered medically necessary** when the following criteria are met:

1. **Diagnosis of chronic respiratory failure due to progressive neuromuscular disease** (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord injuries, spinal muscular atrophy, diaphragmatic paralysis, myasthenia gravis, amyotrophic lateral sclerosis) or severe chest wall disorder (e.g., kyphoscoliosis, asphyxiating thoracic dystrophy); **AND**

2. **Mechanical ventilation required** due to respiratory insufficiency with **one or more** of the following:
   a. Arterial oxygen (O_2) saturation < 88% for 5 consecutive minutes during nocturnal oximetry.
   b. Arterial partial pressure of carbon dioxide ($PaCO_2$) ≥ 45 mm Hg (6.0 kPa).
   c. Maximal inspiratory pressures < 60 cm/H2O.
   d. Forced vital capacity < 50% predicted.

OR

3. **Diagnosis of chronic obstructive pulmonary disease (COPD)** and **one or more** of the following:
   a. Palliative care in patient with end-stage disease and advance directive stating no desire for intubation; **OR**
   b. Chronic hypercapnia and **ALL** of the following:
      - Patient has documented failure of BPAP (including both simple and advanced modes, such as average volume-assured pressure support [AVAPS] and intelligent volume-assured pressure support [iVAPS]) to improve hypercapnia and/or oxygen saturation level; **AND**
      - Prescription for a non-invasive ventilator is written by a pulmonologist (or arrangements have been made for pulmonary follow-up within 3 months); **AND**

OR

4. **Diagnosis of Obesity Hypoventilation Syndrome (OHS)** and **ALL** of the following:
   a. Body mass index ≥ to 30 kg/m^2.
   b. Daytime hypercapnia with $PaCO_2$ greater than 45 mmHg (6.0 kPa) without other etiology (e.g., kyphoscoliosis, lung parenchymal disease, myopathy, severe hypothyroidism).
   c. Sleep-disordered breathing or hypoventilation on polysomnography, as indicated by **one or more** of the following:
      - Apnea-hypopnea index of ≥ 5.
      - Increase in $PaCO_2$ during sleep by more than 10 mm Hg (1.3 kPa) above value while awake.
      - Significant oxygen desaturation (e.g., O2 < 90%) not explained by obstructive apneas or hypopneas.
      - TSH level does not demonstrate hypothyroidism.
   d. Failure to improve arterial oxygen saturations and/or hypercapnia on CPAP or BPAP devices.
   e. Diagnosis and prescription for the device must be made by a pulmonologist or other relevant specialty physician.
   f. The NIPPV device is FDA approved for the clinical indication(s).
   g. 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)

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- 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.

OR

5. **A BPAP or CPAP device is not appropriate** when the Member meets **one or more** of the criteria below:
   a. Chronic respiratory insufficiency fails to improve with a BPAP device (both simple and advanced modes).
   b. Settings or functionality required by patient is not available with a BPAP device (both simple and advanced modes), as indicated by **one or more** of the following:
      - Alarms required by patient are not available on a BPAP device.
      - Daytime ventilation using mouthpiece required.
      - The pressure range delivered by the device (e.g., expiratory or inspiratory pressure) is not appropriate for the patient.
      - Volume-assured pressure support (e.g., AVAPS or iVAPS) or volume control mode is required (e.g., OHS).
   c. Ventilated patient requires cough assistance via volume ventilator's breath stacking capability.
   d. Ventilation is required 24 hours a day.

** Per coding guidelines, when BPAP is documented and performed, CPT 94660 (Continuous positive airway pressure ventilation (CPAP), initiation and management) is the appropriate code as BPAP is a non-invasive mechanical ventilation that includes (CPAP) and pressure support ventilation

Continuation of Therapy

For establishment of **continued medical necessity** beyond 3 months, the medical records should document that the member has been compliantly using the device (an average of 4 hours per 24-hour period, and that the member is benefiting from its use. Approval of continuation of use also requires that indications for the initial approval above are still be met. The following is required for continuation review:

- Compliance with use is reported every three months including documentation of compliant use of the device monitor for an average of 4 or more hours per 24 hours (includes documentation from the requesting provider stating continued benefit of use).
- Initial rental authorization of the device is for 90 days. Compliance is confirmed using a smartcard or other similar report. This verification should be completed within the first 90 days of therapy to assist with long-term rental authorizations. (Note: Smartcards are an important part of NIPPV management and are not separately reimbursable).
- Documentation for a specialist referral.
- Documentation of symptomatic improvement with the use of a ventilator.
- Documentation of a sleep study if treatment is for severe obstructive sleep apnea.
- Documentation of pulmonary function tests and/or arterial blood gases if treatment is for severe COPD or OHS.

Limitations and Exclusions

Home non-invasive positive pressure ventilators **are excluded and not medically necessary** for the treatment of **ANY** of the following conditions or scenarios:

1. Obstructive sleep apnea as the clinical outcomes have not been shown to be superior to other standard treatments (e.g., CPAP, BPAP).
2. Other conditions/diseases, including but not limited to cystic fibrosis, due to insufficient evidence in the peer reviewed medical publications.

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3. Chronic stable COPD without hypercapnia, and central sleep apnea or heart failure.
4. Acute respiratory distress syndrome.
5. Ventilation is required continuously (24 hours/day).

Due to limited evidence-based support, contraindications include, but are not limited to:

- Altered mental status or confusion.
- Drowsiness or loss of consciousness.
- Excessive mucus production or respiratory secretion.
- Facial trauma or other abnormalities.
- Hemodynamic instability.
- Nausea and/or vomiting.
- Respiratory arrest.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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

Neuromuscular or Chest Wall Disorders

Delorme et al. (2023) completed a systematic review and meta-analysis to determine if the intensity of home non-invasive ventilator settings affected outcomes in patients with neuromuscular or chest-wall disorders. Non-invasive ventilator intensity was defined as "the product of pressure support (or tidal volume) and backup rate." The primary outcome was diurnal $PaCO_2$ levels with secondary outcomes being daily non-invasive ventilator usage, interface type, nocturnal oxygenation, and sleep quality. A total of seven studies with 192 participants (n=113 neuromuscular, n=63 chest wall disorder) were included in the analysis. Results for diurnal $PaCO_2$ levels showed that the intensity of non-invasive ventilator settings was not associated with significant differences in $PaCO_2$ levels. However, a greater amount of daily usage was associated with lower $PaCO_2$ levels as was lower baseline $PaCO_2$ values. Regarding oxygenation, higher partial pressure of arterial oxygen (PaO_2) levels were associated with higher baseline PaO_2 values and higher daily usage. Disease category (neuromuscular vs. chest wall disorders) was associated with whether non-invasive ventilator setting intensity impacted PaO_2 levels. Researchers noted greater reductions in $PaCO_2$ values in higher baseline $PaCO_2$ values and higher non-invasive ventilator setting intensity in patients with chest wall disorders. The PaO_2 levels of patients with neuromuscular disorders was negatively impacted by more intense non-invasive ventilator settings while patients with chest wall disorders typically experienced an improvement in PaO_2 levels. There was no significant association noted between non-invasive ventilator setting intensity and interface type or daily non-invasive ventilator usage.

A systematic review conducted by Annane et al. (2014) studied quasi-randomized or RCTs of participants of all ages with neuromuscular or chest wall disorder-related stable chronic hypoventilation of all degrees of severity, receiving any type and any mode of long-term nocturnal mechanical ventilation. The assessment included 10 trials with a total of 173 participants. Roughly half of the trials were at low risk of selection, attrition or reporting bias, and almost all were at high risk of performance and detection bias. Four trials reported mortality data in the long term. The authors concluded that Current evidence on the therapeutic benefit of mechanical ventilation is of very low quality, but is consistent, suggesting alleviation of the symptoms of chronic hypoventilation in the short term. In four small studies, survival was prolonged and unplanned hospitalization was reduced, mainly in participants with motor neuron diseases. 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 trials should assess the long-term

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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.

For restrictive disorders of the chest wall (e.g., kyphoscoliosis, fibrothorax, asphyxiating thoracic dystrophy), available evidence demonstrates at least moderate net benefit. A systematic review completed by Hannan et al. (2014) examined the effect of NIPPV on patient reported outcomes and survival for individuals with or at risk for chronic respiratory failure. Eighteen studies were included, and overall study quality was weak. For restrictive thoracic disease, measures of dyspnea, sleep quality, physical function and health, mental and emotional health and social function improved.

Cystic Fibrosis

The peer reviewed published medical literature is insufficient to confirm improved outcomes of NIPPV in patients with 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 RCTs 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 (Moran et al. 2017).

Milross et al. (2019) completed a prospective, randomized, parallel group study to evaluate if NIPPV with supplemental oxygen reduced the development of hypercapnia or criteria for failure of therapy over 12 months compared to low-flow oxygen therapy alone in patients with cystic fibrosis and oxygen desaturation. A total of 29 patients were included in the study with 14 being randomized to NIPPV with supplemental oxygen and 15 being randomized to low-flow oxygen therapy. Patients received follow-up at 3, 6, and 12 months. The primary outcome was event free survival, defined as failure of therapy ($PaCO_2$ > 60 mmHg, increase in $PaCO_2$ > 10mmHg from baseline, or an increase in $TcCO_2$ > 10 mmHg from awake to sleep or sleep rises in $TcCO_2$ > 10mmHg), lung transplantation, or death. NIPPV with supplemental oxygen was associated with a significantly higher likelihood of event-free survival (33% at 3 months, 26% at 6 months, and 46% at 12 months) and a lower likelihood of failure of therapy. The number of transplants at each follow-up was cumulative (included the number of transplants from the previous follow-up) and for each follow-up period (3, 6, and 12 months respectively) was 0, 2, and 2 for the NIPPV with supplemental oxygen group and 4, 4, and 5 for the low-flow oxygen therapy group. The number of patients meeting failure of therapy criteria was also cumulative and for each follow-up period (3, 6, and 12 months respectively) was 1, 2, and 4 for the low-flow oxygen therapy group while no patients in the NIPPV with supplemental oxygen group met criteria for failure of therapy. There were no differences noted between either group in terms of arterial blood gases, pulmonary function tests, and hospitalizations. Researchers noted that the small sample size of this study did not allow for demonstration of clinically relevant differences in $PaCO_2$. Researchers also noted certain subgroups of patients with cystic fibrosis may benefit from NIPPV. However, additional high-quality studies with larger sample sizes are needed to verify the results of this study and to determine which subgroups would have the most benefit.

Archangelidi et al. (2019) completed a retrospective review of the UK Cystic Fibrosis Registry to determine the patterns of NIPPV usage, the changes in forced expiratory volume in one second associated with NIPPV use, and the survival of patients following initiation of NIPPV therapy. A total of 1,107 patients in the registry had at least one record with documented NIPPV usage. Adults (age > 16 years) with significantly worse lung function (forced expiratory volume in one second < 40% of predicted) at baseline were noted to have a greater increase in forced expiratory volume in one second following initiation of NIPPV therapy. However, the risk of death and transplant was not impacted by the initiation of NIPPV and was noted to be worse compared to the overall cohort with “approximately 36% of those with at least one non-invasive ventilation record [dying] by the end of follow-up [and] 40% accepted for lung transplant.” Researchers noted a potential bias by indication despite bias mitigation using statistical methods as patients with advanced cystic fibrosis were likely to have exhausted treatment options prior to the initiation of NIPPV.

Obesity Hypoventilation Syndrome (OHS)

For OHS, non-invasive BPAP may not supply sufficient pressure to adequately ventilate some patients with severe restrictive lung disease due to obesity. These patients may require support from a non-invasive home ventilator capable of delivering volume driven support. A multicenter, open label, RCT (Masa et al. 2019) compared CPAP with NIPPV in 2015 patients with OHS and apnea hypopnea index of 30 or greater. At the median follow up was 5.44 years, the mean hospitalization days per patient-year were 1.63 in the CPAP group and 1.44 in the NIPPV group. Adverse events

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were similar in both groups. Therapy complexity was lower in the CPAP group. The authors concluded that given the two methods offer similar long-term effectiveness, CPAP may be the preferred first-line treatment modality given its lower complexity. A review by Selim et al. (2018) notes that approximately 60% of patients with OHS will respond to CPAP therapy, while the remainder generally respond to BPAP therapy.

A multidisciplinary panel conducted a full systematic review to address five clinical questions in development of the American Thoracic Society (ATS) *Clinical Practice Guideline for the Evaluation and Management of Obesity Hypoventilation Syndrome* (Mokhlesi et al. 2019). The guideline provides the following recommendations:

- We suggest clinicians use a serum bicarbonate level <27 mmol/L to exclude the diagnosis of OHS in obese patients with sleep-disordered breathing when suspicion for OHS is not very high (<20%) but to measure arterial blood gases in patients strongly suspected of having OHS.
- We suggest stable ambulatory patients with OHS receive positive airway pressure.
- We suggest CPAP rather than non-invasive ventilation be offered as the first-line treatment to stable ambulatory patients with OHS and coexistent severe obstructive sleep apnea.
- We suggest patients hospitalized with respiratory failure and suspected of having OHS be discharged with non-invasive ventilation until they undergo outpatient diagnostic procedures and positive airway pressure titration in the sleep laboratory (ideally within 2–3 months).
- We suggest nocturnal home therapy with NIPPV be offered if CPAP/BPAP fail to correct hypoventilation.
- We suggest patients with OHS use weight-loss interventions that produce sustained weight loss of 25% to 30% of body weight to achieve resolution of OHS (which is more likely to be obtained with bariatric surgery).

Chronic Obstructive Pulmonary Disease (COPD)

The peer reviewed published medical literature is sufficient and demonstrates at least a moderate net benefit of NIPPV in patients with chronic respiratory failure due to COPD.

Raveling et al. (2021) conducted an updated systematic review to assess the effects of chronic NIPPV at home in people with COPD. The authors included RCTs comparing chronic nocturnal NIPPV in addition to standard care versus standard care alone. Studies investigating people initiated on NIPPV in a stable phase and studies investigating NIPPV commenced after a severe COPD exacerbation were reported and analyzed separately. The primary outcomes evaluated were arterial blood gases, health-related quality of life, exercise capacity (stable COPD), and admission-free survival (post-exacerbation COPD). Secondary outcomes for both populations included lung function, COPD exacerbations and admissions, and all-cause mortality. A total of 21 studies (including 778 people with stable COPD and 364 people with post-exacerbation COPD) met inclusion criteria. Results showed that in all people with COPD who had hypercapnia, chronic NIPPV for 3- and 12- months improved blood gases. In stable COPD, chronic NIPPV also might have improved quality of life, and survival seemed to be better compared to people who were treated with standard care only. There was no relevant benefit of NIPPV on exercise capacity. People using chronic NIPPV after a COPD admission experienced less benefit; carbon dioxide levels decreased, the time to the next hospital admission might have been longer when treated with NIPPV but quality of life and survival were not affected by chronic NIPPV. Confidence in the certainty was good in relation to blood gases. 6or other outcomes, certainty of the evidence is moderate to very low due to participants and researchers not being blinded.

[1]Wilson et al. (2020) completed a meta-analysis and systematic review to “evaluate the association of home NIPPV via BPAP devices and non-invasive home mechanical ventilator devices with clinical outcomes and adverse events in patients with COPD and hypercapnia.” The analysis included a total of 51,085 patients with COPD and hypercapnia. The analysis found that BPAP compared to no device was associated with significantly lower mortality risk (22.31% compared to 28.57%). The need for intubation was also significantly lower (5.34% vs 14.71%) as was all-cause hospital admissions (39.74% vs 75.00%). The use of home BPAP was also associated with fewer emergency department visits, ICU admissions, less dyspnea, and a longer distance on the shuttle walk test. Only two observational studies compared non-invasive home mechanical ventilator use to no device. Analysis showed that non-invasive home mechanical ventilator use was also associated with significantly fewer all-cause hospital admissions but no statistically significant difference in mortality (21.84% vs 34.09%). A total of 23 studies compared NIPPV usage (BPAP and non-invasive home mechanical ventilator devices combined) to no device. NIPPV usage was also associated with significantly lower risk of mortality (22.26% vs 29.20%), lower all-cause hospital admissions (39.74% vs 75.00%), and lower need for intubation (5.34% vs 14.71%). One included RCT (n=40 participants) compared BPAP volume assured pressure support to standard BPAP in terms of mortality and found BPAP volume assured pressure support to be associated with lower mortality (5.00% vs 10.00%), although the overall strength of evidence was determined to be insufficient.

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One RCT (n=49 participants) compared BPAP to CPAP and found BPAP was associated with fewer exacerbations (30.43% vs 53.85%). Non-invasive home mechanical ventilator usage was compared to CPAP in one RCT (n=39,700 participants) and found that non-invasive home mechanical ventilator usage was associated with significantly less all-cause hospital admissions ($p<0.001$) and hospital admissions due to respiratory causes ($p=0.01$). However, the quality of evidence was determined to be low.

A RCT of 116 COPD assigned patients with persistent hypercapnia and hypoxemia to home oxygen with or without NIPPV for a 12-month period. Patients using NIPPV experienced longer time to readmission or death (i.e., median 4.3 months vs 1.4 months in the oxygen alone arm) (Murphy et al. 2017).

National and Specialty Organizations

The **Global Initiative for Chronic Obstructive Lung Disease (GOLD)** published its 2024 report with the following recommendations for the use of long-term NIPPV in patients with COPD (GOLD 2023):

- Long-term NIPPV may decrease mortality and prevent re-hospitalization for patients with severe chronic hypercapnia and a history of respiratory failure-related hospitalization(s).
- The need for NIPPV support should be considered individually and an action plan for treatment should be developed and updated as needed.
- The use of NIPPV with home oxygen may significantly prolong the time to hospital readmission or death.
- NIPPV should be prescribed and monitored by clinicians that are familiar with the devices utilized.

An **American Thoracic Society (ATS)** Clinical Practice Guideline on Long-Term Non-invasive Ventilation in Chronic Stable Hypercapnic COPD (Macrea et al. 2020) provides the following five evidence-based recommendations:

- We suggest the use of nocturnal NIPPV in addition to usual care for patients with chronic stable hypercapnic COPD (conditional recommendation, moderate certainty)
- We suggest that patients with chronic stable hypercapnic COPD undergo screening for obstructive sleep apnea before initiation of long-term NIPPV (conditional recommendation, very low certainty)
- We suggest not initiating long-term NIPPV during an admission for acute-on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIPPV at 2–4 weeks after resolution (conditional recommendation, low certainty); 4) we suggest not using an in-laboratory overnight polysomnogram to titrate NIPPV in patients with chronic stable hypercapnic COPD who are initiating NIPPV (conditional recommendation, very low certainty)
- We suggest NIPPV with targeted normalization of $PaCO_2$ in patients with hypercapnic COPD on long-term NIPPV (conditional recommendation, low certainty).

The **National Institute for Health and Clinical Excellence (NICE)** guideline NG115 (2019) on COPD diagnosis and management states, “Refer people who are adequately treated but have chronic hypercapnic respiratory failure and have needed assisted ventilation (whether invasive or non-invasive) during an exacerbation, or who are hypercapnic or acidotic on long-term oxygen therapy, to a specialist center for consideration of long-term non-invasive ventilation.”

A technology assessment prepared for the **Agency for Healthcare Research and Quality (AHRQ)** by the Mayo Clinic Evidence-based Practice Center ([2]Wilson et al. 2020) evaluated the use of NIPPV in adult patients with chronic respiratory failure due to a variety of primary causes including COPD, thoracic restrictive disorders, neuromuscular disease, and OHS. Randomized and comparative nonrandomized studies that enrolled adults with chronic respiratory failure who used NIPPV for ≥ 1 month at home using a home mechanical ventilator, BPAP device, or CPAP device were selected for inclusion, resulting in a total of 68 studies evaluating 53,733 patients. Study limitations include the inability to fully account for the type of device used, equipment settings, and other respiratory services provided. The following conclusions were made:

- In patients with COPD, home BPAP (compared to no device) was associated with lower mortality, decreased need for intubations, fewer patients with hospital admissions but no difference in the total number of hospital admissions or quality of life.
- In patients with stable COPD, NIPPV compared with no device was associated with no difference in the total number of hospital admissions.
- In patients with COPD and recent exacerbation, NIPPV compared with no device was associated with no difference in mortality (OR=0.66, 95% CI: 0.41 to 1.06), but was associated with fewer hospital admissions

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- In patients with thoracic restrictive diseases, home mechanical ventilators (compared to no device) were associated with lower mortality.
- In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life.
- In patients with OHS, home mechanical ventilators or BPAP (compared to no device) was associated with lower mortality.

The assessment also proposes that future research should look to determine which patient populations would benefit from a home mechanical ventilator versus BPAP device, when to optimally initiate treatment, comparative effectiveness of invasive versus non-invasive 24-hour ventilation, and the consequence of various features and device types on outcomes. The authors note that although RCTs may offer the highest level of evidence, enrolling patients requiring this type of treatment may not be ethical. Thus, other study designs, such as single arm interventional studies, may be the best available option.

The **European Respiratory Society** published a 2019 guideline titled *Long-Term Home Non-Invasive Ventilation for Management of COPD.* The following evidence-based recommendations were made regarding the clinical application of non-invasive ventilation in chronic hypercapnic COPD patients (Ergan et al. 2019):

- Use of non-invasive ventilation in stable hypercapnic COPD.
- Use of non-invasive ventilation in COPD patients following a COPD exacerbation requiring acute non-invasive ventilation.
- Use of non-invasive ventilation settings targeting a reduction in carbon dioxide.
- Using fixed pressure support as first choice ventilator mode.

SUPPLEMENTAL INFORMATION

Chronic hypercapnia defined as $PaCO_2 \geq 50$ mm Hg (6.7 kPa).

Non-invasive positive pressure ventilation may be abbreviated as either NIPPV or NPPV. In addition, non-invasive ventilation, or NIV, may also refer to non-invasive positive pressure ventilation. However, NIV may also refer to non-invasive negative pressure ventilation. The type of ventilation (negative or positive) used typically depends on the disease process. In addition, some studies refer to NIPPV as simply non-invasive ventilation or NIV. NIPPV was used throughout this policy to provide clarity and prevent confusion.

Bilevel positive airway pressure is often abbreviated as BiPAP. However, it is important to note that BiPAP is the trademarked name of a specific device. BPAP and BiPAP refer to the same therapy and BPAP was used throughout this policy to prevent reference to a specific device.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System) Codes

HCPCS	Description
E0466	Home ventilator, any type, used with noninvasive interface (e.g., mask, chest shell)
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

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APPROVAL HISTORY

12/13/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, Supplemental Information, and References.
12/14/2022	Policy reviewed, updated Coverage Policy – included criteria for patients with COPD and for those when BPAP/CPAP is not indicated; added Continuation of Therapy section. IRO Peer Review on October 11, 2022, by a practicing, board-certified physician with specialties in the areas of Pulmonary Disease and Critical Care. IRO Peer review on December 12, 2022, by a practicing, board-certified physician with specialties in the area of Pulmonary Disease.
02/09/2022	Policy reviewed; updated Coverage Policy, Summary of Evidence, and Reference section.
02/08/2021	Policy reviewed, updated references.
04/23/2020	Policy reviewed, updated references.
09/18/2019	Policy reviewed, Summary of Evidence and Reference section updated.
07/16/2018	Policy reviewed; updated Coverage Policy, Summary of Evidence, and Reference section. Added medically necessary criteria for the diagnosis of COPD and chronic restrictive hypoventilation syndrome related to obesity.
12/13/2017	Policy reviewed, no changes to criteria, updated references.
05/23/2016	New policy.

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