

## Medical Policy Manual **Draft Revised Policy: Do Not Implement**

### Non-invasive Positive Pressure Ventilators (In-Home Use)

#### DESCRIPTION

A non-invasive positive pressure ventilator (NIPPV) provides support through a non-invasive interface, such as a nasal or face mask. NIPPV is utilized in the acute care setting as short-term life support therapy for respiratory conditions that generally respond relatively quickly to therapy (e.g., acute-on-chronic respiratory failure, COPD, post-op respiratory distress). Evidence-based data demonstrates that use of NIPPV in hospitalized individuals reduces mortality and morbidity (e.g., nosocomial infections, pneumonia, and length of hospital stay) associated with invasive mechanical ventilation. NIPPV during an acute exacerbation is often applied intermittently or continuously while simultaneously administering medical therapeutics. Following optimal recovery, the individual is weaned and NIPPV treatment is terminated. NIPPV may also be useful in the weaning process from invasive mechanical ventilation.

Recently NIPPV has been explored for use in the homecare environment (e.g., Trilogy™, Newport™, VELA®, iVent, Puritan Bennett 540™, and LTV®). Similar to BiPAP, NIPPV can provide both volume and pressure ventilation, but can be more finely tuned to meet the individual's needs. Home NIPPV may be employed in continuous daily use for ventilator dependent individuals (e.g., neuromuscular diseases, thoracic cage abnormalities, severe chronic obstructive pulmonary disease, and obesity hypoventilation syndrome). NIPPVs are portable with an internal battery that lasts up to six hours.

**This policy does not address other respiratory assist devices; for example, CPAP and BiPAP have an MCG: CPAP ACG: A-0431, BiPAP ACG: A-0994.**

The proposal is to add words or statements in red and delete words or statements with a strike through.

#### POLICY

- Home non-invasive positive pressure ventilators (e.g., Trilogy™, Newport™, VELA®, iVent, Puritan Bennett 54™, and LTV®) are considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Home non-invasive positive pressure ventilators (e.g., Trilogy™, Newport™, VELA®, iVent, Puritan Bennett 540™, and LTV®) for the treatment of obstructive sleep apnea are considered **not medically necessary**.
- Home use of a non-invasive positive pressure ventilators (e.g., Trilogy™, Newport™, VELA®, iVent, Puritan Bennett 540™, and LTV®) for the treatment of all other conditions/diseases are considered **investigational**.
- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered **investigational**.

#### MEDICAL APPROPRIATENESS

- Home use of a non-invasive positive pressure ventilator is considered **medically appropriate** if **ALL** of the following are met:
  - Individual is alert and oriented
  - Individual ~~is able to~~ **can** cough or use an assist device to clear secretions
  - Absence of **ALL** of the following:
    - Anatomic abnormality that precludes mask fitting

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- Excessive secretions
- Swallowing disorder
- Documentation of **ANY ONE** of the following:
  - Initial request for three (3) months with **ANY ONE** of the following diagnoses:
    - **Progressive neuromuscular disease** (e.g., muscular dystrophy, myasthenia gravis, polio, amyotrophic lateral sclerosis) resulting in respiratory insufficiency with **ALL** of the following:
      - Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea
      - Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation
      - Documentation of **ANY ONE** of the following:
        - An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the prescribed FIO<sub>2</sub> is greater than or equal to 45 mm Hg
        - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the prescribed recommended FIO<sub>2</sub>
      - Documentation of **ANY ONE** of the following:
        - Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O
        - Forced vital capacity is less than 50% predicted
    - **Severe thoracic cage disorder** (e.g., post-thoracoplasty for TB, Fibrothorax, asphyxiating thoracic dystrophy) resulting in respiratory insufficiency with **ALL** of the following:
      - Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea
      - Chronic obstructive pulmonary disease does not contribute significantly to pulmonary limitation
      - Documentation of **ANY ONE** of the following:
        - An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the prescribed FIO<sub>2</sub> is greater than or equal to 45 mm Hg
        - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the prescribed recommended FIO<sub>2</sub>
    - **Hypoventilation Syndrome** resulting in respiratory insufficiency with **ALL** of the following:
      - Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea
      - An initial arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the prescribed FIO<sub>2</sub>, is greater than or equal to 45 mm Hg
      - Spirometry shows a forced expired volume in 1 second (FEV<sub>1</sub>) or forced vital capacity (FVC) greater than or equal to 70%
      - Documentation of **ANY ONE** of the following:
        - An arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the prescribed FIO<sub>2</sub>, shows the PaCO<sub>2</sub> worsened by 7 mm HG or more compared to the initial arterial blood gas



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- A facility-based polysomnogram or portable home sleep testing demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events, AHI apnea-hypopnea index less than 5
- Continued home use of a non-invasive positive pressure ventilator for **any of the above diagnoses** after the initial three (3) months if **ALL** of the following are documented:
  - A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device stating **ALL** of the following:
    - Evaluation has been completed
    - Member is compliant using the device (i.e. average of 4 hours per 24-hour period)
    - Member is benefiting from its use
- Severe **Chronic Obstructive Pulmonary Disease (COPD)** resulting in respiratory insufficiency with **ALL** of the following:
  - **Initial request is for six (6) months**
  - ~~Documentation of symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea~~
  - Obstructive Sleep Apnea (OSA) has been ruled out as a predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the individual does not suffer from some form of sleep apnea such as Central Sleep Apnea and/or Complex Sleep Apnea desaturation)
  - ~~Compliant with a continuous positive airway pressure device (CPAP) use and CPAP has failed to relieve symptoms, improve awake hypercapnia and/or nocturnal arterial oxygen desaturation~~
  - Documentation of an arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the prescribed FIO<sub>2</sub>, is greater than or equal to 52 mm Hg
  - ~~Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the prescribed FIO<sub>2</sub> (whichever is higher)~~
  - **Individual continues to demonstrate chronic hypercapnic respiratory failure despite optimized use of a respiratory assist device with backup rate features as demonstrated by **ANY ONE** of the following:**
    - Failure to achieve stabilization or reduction of elevated PaCO<sub>2</sub> levels
    - Failure to achieve at least 20% reduction in PaCO<sub>2</sub> from baseline
    - Persistent symptoms of chronic hypercapnia despite therapy (e.g., headaches, fatigue, daytime somnolence, dyspnea, confusion, or poor sleep quality)
- Continued home use of a non-invasive positive pressure ventilator for COPD after the initial six (6) months if **ALL** of the following are documented:
  - The individual is evaluated at least twice during the first year of therapy: at the end of the initial six (6)-month coverage period and during months seven (7) through twelve (12)
  - The treating clinician documents continued device use for at least four (4) hours per 24-hour period on at least 70% of days during a consecutive 30-day period.

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- ~~Continued home use of a non-invasive positive pressure ventilator after the initial three (3) months if **ALL** of the following are documented:~~
  - ~~A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device stating **ALL** of the following:~~
    - ~~Evaluation has been completed~~
    - ~~Member is compliant using the device (i.e. average of 4 hours per 24 hour period)~~
    - ~~Member is benefiting from its use~~

### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

### ADDITIONAL INFORMATION

The clinical outcomes when using positive pressure ventilation for Obstructive Sleep Apnea (OSA) have not been shown to be superior to other approaches (e.g., CPAP, BiPAP). Further investigation is needed with larger populations to determine appropriate candidates for NIPPV and validate long-term outcomes. Studies are needed that can explore improved compliance, decreased adverse events associated with non-compliance, and validate health outcomes of home NIV for diagnosis other than those stated in the above policy.

### SOURCES

Ankjaergaard, K., Tonnesen, P., Laursen, L., Hansen, E., Andreassen, H., & Wilcke, J. (2016). Home non invasive ventilation (NIV) treatment for COPD patients with a history of NIV-treated exacerbation; a randomized, controlled, multi-center study. *BMC Pulmonary Medicine*. 16, 32. (Level 2 evidence)

BlueCross BlueShield Association. Evidence Positioning System. (4:2026). *Home non-invasive positive airway pressure devices for the treatment of respiratory insufficiency and failure*. (8.01.64). Retrieved September 17, 2026 from <https://mypolicies.italiithealth.us/>. (56 articles and/or guidelines reviewed)

Castillejo, O., de Lucas R., López, M., Resano, B., Rodríguez, P., Caicedo, M., et al. (2015). Noninvasive mechanical ventilation in patients with obesity hypoventilation syndrome. Long-term outcome and prognostic factors. *Archivos de Bronconeumología*, 51 (2), 61-8. Abstract retrieved May 29, 2018 from PubMed database.

CMS.gov: Centers for Medicare & Medicaid Services. Palmetto GBA. (2025, June). *Respiratory assist devices (LCD ID L33800)*. Retrieved September 17, 2026 from <https://www.cms.gov>.

Centers for Medicare & Medicaid Services. CMS.gov. NCD for *noninvasive positive pressure ventilation (NIPPV) in the home for the treatment of chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD)* (240.9). Retrieved September 17, 2026 from <http://www.cms.gov>.

European Respiratory Society & American Thoracic Society. (2017). *Official ERS/ATS clinical practice*

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*guidelines: noninvasive ventilation for acute respiratory failure.* Retrieved February 16, 2021 from <https://www.thoracic.org/statements/index.php>.

Global Initiative for Chronic Obstructive Lung Disease (GOLD). *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2025 report.* Retrieved July 21, 2025 from <https://www.goldcopd.org/2025-gold-report/>.

Liu, Y., Dai, B., Su, J., Peng, Y., Tan, W., & Zhao, H. (2017). Effect of home noninvasive positive pressure ventilation on patients with severe stable chronic obstructive pulmonary disease: a meta-analysis. *Zhonghua Jie He*, 40 (5), 354-362. Abstract retrieved November 13, 2017 from PubMed database.

Murphy, P., Rehal, S., Arbane, G., Bourke, S., Calverley, P., Crook, A., et al. (2017). Effect of home noninvasive ventilation with oxygen therapy vs oxygen therapy alone on hospital readmission or death after an acute COPD exacerbation: a randomized clinical trial. *JAMA*, 317 (21), 2177-2186. (Level 2 evidence)

National Institute for Health and Care Excellence. (2016, February; last update search July 2019). *Clinical guideline: motor neurone disease: assessment and management.* Retrieved December 15, 2021 from [www.nice.org.uk](http://www.nice.org.uk).

National Institute for Health and Care Excellence. (2018, December; last update search July 2019). *Clinical guideline: chronic obstructive pulmonary disease in over 16s: diagnosis and management.* Retrieved April 23, 2020 from [www.nice.org.uk](http://www.nice.org.uk).

U. S. Food and Drug Administration. (2006, January). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K053270. (iVent™) Retrieved June 25, 2013 from <http://www.accessdata.fda.gov>.

U. S. Food and Drug Administration. (2008, December). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K08724. (Newport HT500®) Retrieved June 25, 2013 from <http://www.accessdata.fda.gov>.

U. S. Food and Drug Administration. (2009, March). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K083526. (Trilogy) Retrieved June 25, 2013 from <http://www.accessdata.fda.gov>.

Wilson, M., Dobler, C., Morrow, A., Beuschel, B., Alsawas, M., Benkhadra, R., et al. (2020). Association of home noninvasive positive pressure ventilation with clinical outcomes in chronic obstructive pulmonary disease: A systematic review and meta-analysis. *JAMA*, 323 (5), 455-465. (Level 2 evidence)

### EFFECTIVE DATE

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