

# Noninvasive Home Ventilators



INDEPENDENT CARE HEALTH PLAN

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## Medicare Advantage Medical Coverage Policy

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#### Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## Related Medicare Advantage Medical/Pharmacy Coverage Policies

None.

## Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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NCD	Durable Medical Equipment Reference List	<a href="#">280.1</a>		
LCD LCA	Respiratory Assist Devices	<a href="#">L33800</a> <a href="#">A52517</a> <a href="#">A58822</a> <a href="#">A55426</a>	DME A - Noridian Healthcare Solutions, LLC (DME MAC)  DME B - CGS Administrators, LLC (DME MAC)  DME C - CGS Administrators, LLC (DME MAC)  DME D - Noridian Healthcare Solutions, LLC (DME MAC)	CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT  IL, IN, KY, MI, MN, OH, WI  AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI  AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands

## Description

A ventilator is a machine that helps an individual breathe, or takes over the breathing function completely, by forcing air into the lungs at a preset volume and frequency, reproducing the normal breathing pattern as closely as possible. Ventilators may be classified as invasive or noninvasive.

An invasive mechanical ventilator administers the ventilation via a securely intubated airway, either by way of an endotracheal (ET) tube or a tracheostomy tube. Invasive ventilation is generally continuous; interruption could result in a life-threatening situation.

Noninvasive ventilation (NIV) refers to positive airway pressure delivered via a noninvasive interface (nasal and/or oral mask, mouthpiece or nasal prongs) between the individual and the ventilator. NIV may also be referred to as noninvasive positive pressure ventilation (NPPV). NIV may be used intermittently during the day and/or during sleep, though most frequently they are used at night. Examples of US Food & Drug Administration (FDA) approved NIV devices include, but may not be limited to:

- **Astral 100**
- **Astral 150**
- **Breas Vivo (eg, 30 Bi-Level Ventilator, Vivo 45, Vivo 55, Vivo 65 USA)**

- **Stellar 150**
- [Trilogy 100\\*](#)
- [Trilogy 200\\*](#)
- [Trilogy EVO\\*](#)

These devices can deliver bi-level modes or function as noninvasive ventilators. When these devices deliver bi-level modes, they are considered respiratory assist devices (RAD). NIV refers to devices that deliver true modes of mechanical ventilation. While continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BPAP) devices can be owned, NIV devices require continuous rental payment.

The **Life2000** is an ambulatory noninvasive open ventilation (NIOV) system with a nasal pillow interface. It is a modular system with three different configurations: stationary; ambulatory near the main unit using 50 feet of tubing provided; or ambulatory using a one pound detachable unit that can be worn on the waistband or with a strap for up to 6 hours at a time via the self-contained rechargeable battery.

\* The Trilogy 100, Trilogy 200 and Trilogy EVO are currently the subject of an FDA class I safety recall.<sup>39</sup>

## Coverage Determination

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

iCare members may be eligible under the Plan for a **noninvasive home ventilator** when the following criteria are met:

- Device requested is [FDA-approved](#); **AND**
- The decision to use a ventilator or a BPAP device is made based upon the specifics of each individual's medical condition; **AND**
- Chronic obstructive pulmonary disease (COPD) with **ALL** of the following:
  - Arterial oxygen saturation level is less than or equal to 88% for at least 5 minutes while asleep (minimum recording time of 2 hours)<sup>9</sup>; **AND**
  - Chronic hypercapnia with PaCO<sub>2</sub> greater than or equal to 52 mm Hg<sup>9</sup>; **AND**
  - Prior to initiating therapy, sleep apnea and treatment with a CPAP/BPAP device has been considered and ruled out<sup>9</sup>; **OR**

- Neuromuscular disease (eg, amyotrophic lateral sclerosis [ALS], Guillain-Barre syndrome, muscular dystrophy, post-polio syndrome) with respiratory failure from weakened breathing muscles, as evidenced by at least **ONE** of the following:
  - Arterial oxygen saturation level is less than or equal to 88% for at least 5 minutes while asleep (minimum recording time of 2 hours)<sup>9</sup>; **OR**
  - Chronic hypercapnia with PaCO<sub>2</sub> greater than or equal to 45 mm Hg<sup>9</sup>; **OR**
  - Forced vital capacity (FVC) is less than 50% predicted<sup>9</sup>; **OR**
  - Maximal inspiratory pressure (MIP) is less than 60 cm H<sub>2</sub>O<sup>9</sup>; **OR**
- Obesity hypoventilation syndrome with **BOTH** of the following:
  - Chronic hypercapnia with PaCO<sub>2</sub> greater than or equal to 45 mm Hg<sup>9</sup>; **AND**
  - Forced expiratory volume (FEV1)/FVC greater than or equal to 70%<sup>9</sup>;

**AND either of the following:**

  - Arterial blood gas PaCO<sub>2</sub> is performed while asleep or shortly after awakening that shows an increase in PaCO<sub>2</sub> by at least 7 mm Hg<sup>9</sup>; **OR**
  - Facility based polysomnogram or home sleep study demonstrates oxygen saturation level is less than or equal to 88% for at least 5 minutes while asleep (minimum recording time of 2 hours) that is not caused by obstructive upper airway events<sup>9</sup>; **OR**
- Restrictive thoracic disorders (eg, chest wall deformities, kyphoscoliosis, post-thoracoplasty for TB) with the **EITHER** of the following:
  - Arterial oxygen saturation level is less than or equal to 88% for at least 5 minutes while asleep (minimum recording time of 2 hours)<sup>9</sup>; **OR**
  - Chronic hypercapnia with PaCO<sub>2</sub> greater than or equal to 45 mm Hg<sup>9</sup>; **AND**
- There is a Standard Written Order (SWO) from the healthcare provider for the ventilator<sup>8</sup>; **AND**
- Medical records (eg, provider's office notes, hospital records) support that the specific device is needed for the individual's condition; **AND**
  - Documentation in the medical record supports the medical necessity of the NIV settings ordered and that the respiratory failure cannot be adequately treated with CPAP or BPAP<sup>9</sup>; **AND**

- Forms, templates or letters of medical necessity need to align with medical records to meet Medicare requirements<sup>8</sup>; **AND**
- Certificates of medical necessity, durable medical equipment (DME) information forms, supplier prepared statements and physician attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the ordering physician<sup>8</sup>

### **Continuation of Coverage**

NIV is initially authorized for 90 days rental. Compliance may be verified by a [smartcard](#)<sup>^</sup>. Compliance is defined as usage on average of at least 4 hours per day.<sup>25</sup> Verification of compliance may be determined at any time within the first 90 days of therapy in order to make an extended rental decision.

### **Summary of Evidence**

Some devices can deliver bi-level modes or function as noninvasive ventilators. When these devices are utilized as a respiratory assist device (RAD) deliver bi-level modes (eg, CPAP, automatic positive airway pressure [APAP], BPAP, adaptive support ventilation [ASV], average volume-assured pressure support [AVAPS], intelligent volume-assured pressure support [iVAPS]), they are considered not medically necessary based on Medicare guidance. Medicare does not cover a home ventilator when used for settings that can be provided with BPAP which includes AVAPS mode. Currently there is no published evidence in the peer reviewed literature to support the clinical superiority of these modes.

The Agency for Healthcare Research and Quality (AHRQ) performed a technology assessment on NPPV in the home. AHRQ concluded that the current evidence is insufficient to assess the comparative effectiveness of NPPV device capabilities on patient outcomes specifically comparing home mechanical ventilators to BPAP devices.<sup>1</sup>

**^Smartcards are used to view compliance data of an individual on NIV and are an integral component of NIV management and are therefore not separately reimbursable.**

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

### **Coverage Limitations**

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following indications for noninvasive home ventilators will not be considered medically reasonable and necessary:

- Acute respiratory distress syndrome (ARDS); **OR**
- Acute respiratory failure; **OR**
- Treatment is solely for obstructive sleep apnea (OSA)

Ventilators fall under the Frequent and Substantial Servicing (FSS) payment category, and payment policy requirements preclude FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. Devices classified as HCPCS code E0466 or E0467 when used to provide CPAP or BPAP (with or without backup rate) therapy, regardless of the underlying medical condition, will not be paid in the FSS payment category. A ventilator is not eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Claims for ventilators used to provide CPAP or bi-level CPAP therapy for conditions described in the RAD policy will be denied as not reasonable and necessary.<sup>9</sup>

### **Ambulatory NIOV System**

iCare members may **NOT** be eligible under the plan for **ambulatory NIOV system (eg, Life2000)**.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

### **Summary of Evidence**

#### ***Ambulatory NIOV System***

A comparative study evaluated improvements in exercise tolerance comparing four methods: breathing room air, using NIOV with compressed air, using NIOV with compressed oxygen and using oxygen via nasal cannula. There were 15 males with COPD included in the study. Although the study showed that NIOV with compressed oxygen produced exercise endurance improvements and dyspnea reductions in patients with severe hypoxemic COPD, there were no significant differences in transcutaneous PCO<sub>2</sub> or gas exchange efficiency among the treatments.<sup>20</sup>

A study performed a bench evaluation of the NIOV system, but there were several limitations. Although the study concluded that the NIOV system results in ventilation of the lung model and stable inspired oxygen concentration (FIO<sub>2</sub>), there were several limitations in this study including the use of a lung model and using a set of compliance and resistance characteristics based on disease states which is not completely representative of the target patient population. Patient studies are required to determine the utility of the device.<sup>18</sup>

A prospective, open-label, crossover study evaluated patients performing a selected activity of daily living (ADL) with standard oxygen therapy versus performing the same ADL using the NIOV system. ADL endurance time, oxyhemoglobin saturation measured by pulse oximeter, dyspnea, fatigue, and discomfort scores were documented. Although this study concluded that the NIOV system can improve ADL performance in the home setting compared to standard oxygen therapy, there were several limitations. There was a small sample size of 29 patients, and the patients were allowed to select the ADL they wanted to perform therefore direct comparisons between patients were not feasible. Data was also collected during a single at-home visit which limits conclusions regarding long-term outcomes.<sup>7</sup>

A review of the current medical literature indicates a continued lack of randomized, blinded clinical studies examining long-term clinical outcomes that establish the value of the ambulatory NIOV system. A low-quality body of evidence suggests that the ambulatory NIOV system can improve exercise endurance, dyspnea reductions and ADL performance; however, long-term follow-up from larger randomized, sham-controlled, blinded studies is needed to properly assess efficacy and safety.

### Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
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	

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## Change Summary

- 01/01/2024 New Policy.