# Noninvasive Home Ventilators

Humana®

**Effective Date:** 07/25/2024
**Revision Date:** 07/25/2024
**Review Date:** 07/25/2024
**Policy Number:** HUM-0560-011
**Line of Business:** Commercial

## Medical Coverage Policy

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## 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 200***
- **Trilogy EVO***

* The Trilogy 200 and Trilogy EVO are currently the subject of an FDA class I safety recall.[32]

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.

While these noninvasive ventilators are capable of delivering positive airway pressure, they are more advanced than traditional devices used for the treatment of obstructive sleep apnea (OSA).

Another variation of NIV is the **Biphasic Cuirass Ventilation (BCV)** system, which uses a lightweight plastic shell that includes a foam seal to form an airtight fit around the individual. The shell is then connected via a hose to the power unit. This type of ventilator works on the theory of negative pressure breathing, which is purported to function in the same manner as the inspiration and expiration cycles of unassisted (normal) breathing. In its inspiratory phase, the negative pressure from the BCV pulls the diaphragm down, helping to draw air into the lungs, and in its expiratory phase uses positive pressure to push the air back out of the lungs. This device also offers high-frequency chest wall oscillation and an assisted cough function, without the need to change the interface or devices. **(Refer to Coverage Limitations section)**

**Noninvasive open ventilator (NIOV)** is a battery powered, wearable, volume ventilator that augments the individual's spontaneous breathing. The NIOV administers this physician-prescribed volume to the individual via a noninvasive interface, such as a face mask, nasal mask, orofacial mask, or nasal prongs (nasal pillows). The ventilator is small and light enough to be worn on the individual's belt or slung over their shoulder. It is connected to a separate, third party, air or oxygen gas supply. An example of a FDA-approved device includes but may not be limited to: **Life2000 Ventilation System.**[14] **(Refer to Coverage Limitations section)**

**Dual-function respiratory device** combines ventilation with cough stimulation capabilities; they can be used with tracheal intubation, a mask or mouthpiece. Integrated ventilation/cough stimulation allows the individual's caregiver to switch between the two modes without having to change or disconnect circuits. Cough stimulation is activated by pushing a button on the ventilator's touchscreen control pad. The ventilator applies insufflation (positive pressure) followed by rapid exsufflation (negative pressure), which mimics the actions of a natural cough. The ventilator has a suction feature that operates during cough stimulation and a cannister for suctioned secretions. When the cough stimulation cycles are finished, ventilation automatically resumes. Examples of FDA-approved devices include but may not be limited to:

**VOCSN VC** and **VC Pro** ventilators. VOCSN stands for ventilation, oxygen, cough, suction, and nebulizer, which captures the integrated components and capabilities of the VOCSN ventilator product line.[13] **(Refer to Coverage Limitations section)**

The **Lung Assist Exsufflation Belt** is a device that has been proposed as an alternative to noninvasive home ventilators. It is described as a stand-alone intermittent abdominal daytime pressure ventilation device, which is a wearable, noninvasive belt that works by forcing diaphragmatic exhalation; inhalation occurs passively. **(Refer to Coverage Limitations section)**

## Coverage Determination

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

- Absence of contraindications; **AND**
- Device requested is FDA-approved; **AND**
- Chronic obstructive pulmonary disease (COPD) with **ALL** of the following:
  - Absence of clinical evidence of OSA/central sleep apnea (CSA)**** OR a previously negative polysomnogram (sleep study); **AND**
  - Chronic hypercapnia with $PaCO_2$ greater than or equal to 52 mmHg; **OR**
- COPD **with OSA** when traditional positive airway pressure devices (eg, CPAP, BIPAP) have failed to improve hypercapnia or oxygen saturation level; **OR**
- Neuromuscular diseases (eg, amyotrophic lateral sclerosis [ALS], Guillain-Barre syndrome, muscular dystrophy, post-polio syndrome) with respiratory insufficiency, as evidenced by:
  - Arterial oxygen saturation less than or equal to 88% for 5 consecutive minutes during nocturnal oximetry; **OR**
  - Arterial $PaCO_2$ greater than or equal to 45 mmHg; **OR**
  - Forced vital capacity (FVC) at less than 50% of predicted; **OR**
  - Maximum inspiratory pressure (MIP) less than 60 cm $H_2O$; **OR**
- Obesity hypoventilation syndrome with **ALL** of the following:
  - Body mass index (BMI) greater than 30; **AND**
  - Daytime hypercapnia with $PaCO_2$ greater than or equal to 45 mmHg; **AND**
  - Polysomnogram (sleep study) has ruled out OSA or CSA; **OR**

- Restrictive thoracic cage abnormalities (eg, chest wall deformities, kyphoscoliosis) with the following:
    - Absence of clinical evidence of OSA/CSA** OR a previously negative polysomnogram (sleep study);

**AND either of the following:**

- Hypercapnia with $PaCO_2$ greater than or equal to 45 mmHg; **OR**
- Oxygen saturation less than or equal to 88% for 5 consecutive minutes during nocturnal oximetry

****Clinical evidence of OSA** may include excessive daytime sleepiness (eg, inability to remain fully awake or alert) despite a full night's sleep, nonrestorative sleep (waking up from sleep without feeling rested), bed partner reports loud snoring, gasping, choking, snorting or interruptions in breathing while sleeping. **Clinical evidence of CSA**, which is the result of either a neurological injury or disease process that interferes with the transmission of signals to the muscles that control breathing, may include repetitive cessation or decrease in ventilatory effort during sleep and symptoms of disrupted sleep, such as excessive daytime sleepiness, inattention and poor concentration.

**Continuation of Coverage**
NIV is initially authorized for 90 days rental. Compliance may be verified by a smartcard**^**. Compliance is defined as usage of at least 4 hours per 24-hour period, 5 days each week over a 30-day period. Verification of compliance may be determined at any time within the first 90 days of therapy in order to make an extended rental decision.

**^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.**

## Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **noninvasive home ventilators** for any indications other than those listed above including, but not limited to:

- Acute respiratory distress syndrome (ARDS); **OR**
- Treatment is solely for OSA; **OR**
- Ventilation is required continuously (24 hours/day)

This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **NIV** for any of the following contraindications:

- Confusion or altered mental status; **OR**
- Drowsiness or loss of consciousness; **OR**

- Excessive respiratory secretions (mucus production); **OR**
- Facial abnormalities/trauma; **OR**
- Hemodynamic instability; **OR**
- Nausea/vomiting; **OR**
- Presence of a tracheostomy; **OR**
- Respiratory arrest

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

**Duplicate Equipment**

Please consult the member's individual certificate regarding Plan coverage for duplicate or similar equipment, which includes, but may not be limited to, equipment with the same function for use in another location (eg, school, second residence, travel, work) as it may be excluded by certificate. In the absence of a certificate exclusion, this is considered not medically necessary as defined in the member's individual certificate.

Humana members may **NOT** be eligible under the Plan for a **dual-function respiratory device**. This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **any of the following noninvasive ventilators** including, but may not be limited to:

- Biphasic cuirass ventilation (BCV); **OR**
- Noninvasive open ventilator (NIOV)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the **Lung Assist Exsufflation Belt** for any indication. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

## 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** |
| A4468 | Exsufflation belt, includes all supplies and accessories | **Not Covered**<br><br>**New Code Effective 01/01/2024** |
| E0466 | Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell) | **Not Covered if used to report any ventilator outlined in Coverage Limitations section** |
| 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 | **Not Covered if used to report any ventilator outlined in Coverage Limitations section** |
| E0468 | Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions | **Not Covered**<br><br>**New Code Effective 04/01/2024** |
| K1021 | Exsufflation belt, includes all supplies and accessories | **Not Covered**<br><br>**Deleted Code Effective 12/31/2023** |

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## Change Summary

07/25/2024 Annual Review, Coverage Change. Updated Coding Information