

## Back-Up Ventilators in the Home Setting

<b>Policy ID:</b>	HHO-DE-MP-1006
<b>Approved By:</b>	Highmark Health Options – Market Leadership
<b>Provider Notice Date:</b>	10/20/2023
<b>Original Effective Date:</b>	11/20/2023
<b>Annual Approval Date:</b>	11/2024
<b>Last Revision Date:</b>	10/04/2023
<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 5

### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary back-up ventilators in the home setting, for use as a "back-up" machine.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**Mechanical Ventilation** – A life support system designed to replace or support normal ventilatory lung function (AARC, 2007).

**Invasive Mechanical Ventilation** – The delivery of positive pressure to the lungs via an endotracheal or tracheostomy tube. It is most often used to fully or partially to replace the function of spontaneous breathing and gas exchange.

### PROCEDURE

Prior authorization is required.

Reauthorization is required at least every six months subject to member's compliance of at least 80% of prescribed use.

Home positive pressure ventilation with an invasive interface (e.g., tracheostomy) is clinically proven and, therefore, medically necessary life support when the following criteria are met (American Association for Respiratory Care, 2007; Make, 1998):

- The ventilator is approved by the U.S. Food and Drug Administration for use in the home and with an **invasive interface**.
- The member meets discharge criteria for medical, respiratory, and psychological stability (American Thoracic Society, 2005; Sterni, 2016).
- A comprehensive discharge plan is in place to ensure a safe physical environment and adequate resources for care in the home (American Thoracic Society, 2005; Sterni, 2016).
- Any of the following indications:
  - Member meets criteria for noninvasive ventilation but has uncontrollable airway secretions or impaired swallowing leading to chronic aspiration and repeated pneumonias.
  - Member has persistent symptomatic respiratory insufficiency and failure of or inability to tolerate noninvasive ventilation.
  - Member has severely weakened or paralyzed respiratory muscles requiring at least 20 hours of ventilator support, and member or provider prefers invasive ventilation.

Home positive pressure ventilation with a **noninvasive** interface is medically necessary for pediatric members prescribed continuous or bilevel positive airway pressure when both criteria are met (American Association for Respiratory Care, 2004):

- The prescription cannot be delivered using a traditional respiratory-assist device.
- The positive pressure ventilator has noninvasive capabilities and has been approved for home use in this population.

The multifunction ventilator (i.e., the Ventilation, Oxygen, Cough, Suction, Nebulization device, Ventec Life Systems, Bothell, Washington) is clinically proven and, therefore, medically necessary for members who meet criteria for both home positive pressure ventilation and at least one of the following durable medical equipment: portable oxygen concentrator; cough stimulator; suction pump; or nebulizer.

A second ventilator in the home setting is medically necessary for any of the following indications (American Association for Respiratory Care, 2007; Make, 1998):

- For members who require at least 18 hours of mechanical ventilation of life support per day.
- For members who live in an area where a replacement ventilator cannot be provided within one hour from an EMS without compromising the member's medical condition.

Battery backup is medically necessary for members on home mechanical ventilation for any of the following indications (Make, 1998):

- When power failures are common.
- When a member may suffer adverse consequences during even brief outages.

In some situations, an individual qualifies for coverage for both a primary ventilator and a secondary ventilator, typically when each ventilator is used for a different medical purpose. The Centers for Medicare & Medicaid Services (CMS) national coverage determination for ventilators provides the following examples (not all inclusive) of appropriate scenarios.

- One type of ventilator (e.g., a negative pressure ventilator with a chest shell) is required for part of the day and a different type of ventilator (e.g., positive pressure ventilator with a nasal mask) is required during the rest of the day.
- A portable ventilator is mounted on the wheelchair for use during the day and individual requires a stationary ventilator for use while in bed.

Although there are no definitive criteria for when a secondary ventilator would be appropriate for an individual who requires a ventilator non-continuously, a consensus statement from the technical expert panel report from the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society strongly suggests that, for individuals with restrictive respiratory disorders who have progressed to the use of home mechanical ventilation (HMV) for more than 18 hours a day, a second device should be offered and at least one of the two devices should be portable so that wheelchair attachment and mobility are possible.

### LIMITATIONS

Home invasive positive pressure ventilation is considered not medically necessary life support for non-life-threatening conditions or when used as a respiratory assistance device (e.g., continuous positive airway pressure, auto-titrating positive airway pressure, bilevel positive airway pressure, or adaptive servo-ventilation) as treatment for any of the following documented diagnoses:

- Obstructive sleep apnea.
- Central sleep apnea.
- Hypoventilation syndrome (primary cause not obstructive sleep apnea or central sleep apnea).
- Restrictive thoracic disorder with no or mild chronic obstructive pulmonary disease by history or testing.
- Severe chronic obstructive pulmonary disease.

Contraindications to mechanical ventilation provided in the home setting include (American Academy of Pediatrics (Carlo, 1999); American Association for Respiratory Care, 2007; American Thoracic Society, 2005; Make, 1998):

- Lack of an appropriate discharge plan.
- Unsafe physical environment as determined by the patient's discharge planning team.
- Presence of fire, health or safety hazards including unsanitary conditions.
- Inadequate basic utilities (such as heat, air conditioning, electricity including adequate amperage and grounded outlets).
- Inadequate resources for care in the home (e.g., financial, personnel).
- Inadequate medical follow-up.
- Inability of member to care for self if no caregiver is available.
- Inadequate respite care for caregivers.
- Inadequate numbers of competent caregivers (a minimum of two competent caregivers is required).
- Member's choice not to receive home mechanical ventilation.
- Presence of physiologic instability of a medical condition requiring a higher level of care or resources than can be provided in the home. Examples include (American Association for Respiratory Care, 2007):
  - Fraction of inspired oxygen requirement > .40.
  - Large fluctuations in fraction of inspired oxygen.
  - Positive end expiratory pressure > 10 cm H<sub>2</sub>O.
  - Need for continuous invasive monitoring in adult patients.
  - Lack of mature tracheostomy.
  - Hemodynamic instability.

- Inadequate treatment of underlying reversible disorders that may contribute to the member's symptoms.

### POST-PAYMENT AUDIT STATEMENT

The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

### PLACE OF SERVICE: OUTPATIENT

### CODING REQUIREMENTS

CPT Code	Modifier	Description
<b>E0465</b>	<b>-TW</b>	Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube).
<b>E0467</b>	<b>-TW</b>	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.

\*\*Note: -TW modifier indicates back-up durable medical equipment

### REIMBURSEMENT

All equipment must be billed to the primary insurance, regardless of if this is a covered benefit or not.

### References

American Association for Respiratory Care (AARC) Clinical Practice Guideline: Long-term invasive mechanical ventilation in the home. Original publication: *Respir Care*. 1995; 40(12):1313-1320. 2007 Update with Revisions. *Resp Care*. 2007; 52(1):1056-1062. Available at: <https://www.aarc.org/wp-content/uploads/2014/08/08.07.1056.pdf>. Accessed on June 9, 2022.

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: Durable Medical Equipment. Reference List NCD #280.1. Effective September 1986; most recent update: May 5, 2005. Available at:

<http://www.cms.gov/medicarecoveredatabase/details/ncddetails.aspx?NCDId=190&ncdver=2&NCAId=3&ver=5&NcaName=Air-Fluidized+Beds+for+Pressure+Ulcers&bc=ACAAAAAAIAAA&>. Accessed on June 9, 2022.

Centers For Medicare & Medicaid Services. Noninvasive positive pressure ventilation in the home. Available at: <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id108TA.pdf>. Accessed on June 9, 2022.

American Association for Respiratory Care. AARC clinical practice guideline. Long-term invasive mechanical ventilation in the home — 2007 revision & update. *Respir Care*. 2007;52(8):1056-1062. Doi: <http://rc.rcjournal.com/content/52/8/1056/tab-pdf>.

Make BJ, Hill NS, Goldberg AI, et al. Mechanical ventilation beyond the intensive care unit. Report of a consensus conference of the American College of Chest Physicians. *Chest*. 1998;113(5 Suppl):289s-344s. Doi: 10.1378/chest.113.5\_supplement.289s.

American Thoracic Society. Statement on home care for patients with respiratory disorders. Am J Respir Crit Care Med. 2005;171(12):1443-1464. Doi: 10.1164/rccm.2504001.

Stemi LM, Collaco JM, Baker CD, et al. An official American Thoracic Society clinical practice guideline: Pediatric chronic home invasive ventilation. Am J Respir Crit Care Med. 2016;193(8):e16-35. Doi: 10.1164/rccm.201602-0276ST.

American Association for Respiratory Care. AARC clinical practice guideline. Application of continuous positive airway pressure to neonates via nasal prongs, nasopharyngeal tube, or nasal mask — 2004 revision & update. American Association for Respiratory Care website. <https://www.aarc.org/wpcontent/uploads/2014/08/09.04.1100.pdf>. Published September 2004.

Carlo WA, Ambalavanan N. Conventional mechanical ventilation: Traditional and new strategies. Pediatr Rev. 1999;20(12):e117-e126. <https://pubmed.ncbi.nlm.nih.gov/10587537/>

Centers for Medicare & Medicaid Services, Correct Coding and Coverage of Ventilators. 2020.

Centers for Medicare & Medicaid Services, National Coverage Determination (NCD) Durable Medical Equipment (DME) Reference List 280.1. 2005.

Hill et al., Chest 2021, 160: e389-e97.

**POLICY UPDATE HISTORY**

12.8.2022	Approved in Reimbursement Policy
12.19.2022	Approved in Governance