

Ventilators

Description

A **ventilator** is a device which moves air in and out of the lungs for an individual who requires mechanical assistance to breathe.

- **Invasive ventilation (E0465)**: Home ventilator, any type, used with invasive interface (e.g., tracheostomy tube).
- Non-invasive ventilation (E0466): Home ventilator, any type, used with non-invasive interface (e.g., mask, chest shell).
- Multifunction ventilator (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.

Policy Guidelines

Medicare Member Coverage Criteria:

Refer to National Coverage Determination (see NCD CAG-00465N) for additional coverage criteria.

Non-Medicare Member Coverage Criteria:

A home ventilator may be covered for members who require mechanical assistance to breathe, and:

- When prescribed by the member's treating practitioner.
- When the coverage criteria for the specific (E0465, E0466 or E0467) below are met.

Coverage Criteria

An **invasive home ventilator (E0465)** is considered reasonable and necessary when the following criteria is met.

- The member has a qualifying diagnosis such as:
 - o A neuromuscular disease,
 - o thoracic restrictive disease, or
 - o chronic respiratory failure consequent to chronic obstructive pulmonary disease (see criteria below).



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Home Mechanical Ventilators for diagnosis of chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD).

(a) Initial Coverage Criteria

Northwood will cover a home mechanical ventilator (HMV) used in a volume targeted mode as treatment for a patient with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD) who exhibits certain clinical characteristics.

- (i) An HMV is covered for an initial 6-month period for patients with COPD when all of the following criteria are met:
 - The patient exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas during awake hours while breathing his/her prescribed FiO2; and
 - Sleep apnea is not the predominant cause of the hypercapnia (Formal sleep testing is not required if, per the treating clinician, the patient does not experience sleep apnea as the predominant cause of the hypercapnia.); *and*
 - The patient demonstrates at least one of the following characteristics:
 - o Requires oxygen therapy at an FiO2 \geq 36% or \geq 4L nasally, or
 - o Requires ventilatory support for more than 8 hours per 24-hour period, or
 - o Requires the alarms and internal battery of an HMV, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted as determined by the treating clinician, *or*
 - o Per the treating clinician, none of the below are likely to be achieved with consistent use of a RAD with backup rate feature for at least 4 hours per 24-hour period on at least 70% of days because the patient's needs exceed the capabilities of a RAD as justified by the patient's medical condition:
 - Normalization (< 46 mmHg) of PaCO2, or
 - Stabilization of a rising PaCO2, or
 - 20% reduction in PaCO2 from baseline value, *or*
 - Improvement of *at least one* of the following patient symptoms associated with chronic hypercapnia:



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- headache
- fatigue
- shortness of breath
- confusion
- sleep quality

(ii) Home Mechanical Ventilator Use Upon Hospital Discharge

Northwood will cover in the home an HMV used in a volume targeted mode immediately upon hospital discharge for an initial 6-month period for patients with acute on chronic respiratory failure due to COPD, if the patient's needs exceeded the capabilities of a RAD (with or without backup rate feature) and required usage of a ventilator within the 24-hour period prior to hospital discharge and the treating clinician determines that the patient is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

(b) Continuing Usage Criteria for an HMV

Patients must be evaluated at least twice within the first year after initially receiving an HMV. Evaluations must occur by the end of the six-month initial coverage period and again during months 7-12.

First evaluation:

By 6 months after receiving initial coverage of an HMV, the treating clinician must establish that usage criteria are being met. The patient must be determined by a clinician to use the HMV at least 4 hours per 24-hour period, on at least 70% of days in a 30-day period.

Second evaluation:

After month 6 of initially receiving an HMV, the treating clinician must establish that the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month.

(c) Masks for HMVs

For patients who use an HMV in a volume targeted mode: 1) for greater than 8 hours in any 24-hour period; and 2) use an oronasal mask at night, a different interface (e.g., mouthpiece ventilation or nasal mask) is covered for daytime hours. Note, coverage of such supplies does not exclude coverage of additional supplies necessary for the effective use of the HMV.

Non-invasive *negative* pressure ventilation (E0466) is medically necessary DME for members who meet the following criteria:



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Member has been diagnosed with any of the following conditions:

- Central hypoventilation (i.e., apnea not due to airway obstruction); or
- Chest wall deformity (e.g., post-thoracoplasty for tuberculosis, etc.); or
- Slowly progressive neuromuscular diseases (e.g., muscular dystrophies, poliomyelitis, multiple sclerosis, spinal cord diseases, diaphragmatic paralysis, etc.); *and*

Member has chronic stable or slowly progressive respiratory failure that meets any of the following criteria:

- Significant CO₂ retention (PaCO₂ greater than 50 mm Hg); or
- Mild CO₂ retention (PaCO₂ greater than 45 mm Hg) with any of the following symptoms:
 - o Cognitive dysfunction, or
 - Daytime hypersomnolence, or
 - o Morning headache, or
 - O Documented nocturnal hypoventilation or oxygen desaturation (with oxyhemoglobin saturation less than 88 % for at least 5 minutes).

Non-invasive negative pressure ventilation is considered experimental and investigational for all other indications (e.g., acute hypoxemic respiratory failure) because its effectiveness for indications other than the ones listed above has not been established.

Note: Non-invasive negative pressure ventilation may be given to members with respiratory failure with the use of devices that apply intermittent negative extra-thoracic pressure and augment tidal volume. These include body ventilators and the poncho wrap.

Codes (E0457) Cuirass Chest Shell and (E0459) Chest Wrap may be considered medically necessary for use with the non-invasive negative pressure ventilator system.

New ventilator members requiring the **multi-function ventilator** must be prescribed the (**E0467**) and meet the medical necessity coverage criteria for a ventilator and at least one of the four additional functions (oxygen concentrator, cough stimulator, suction pump and nebulizer). Note: The member may not utilize separate stand-alone devices when an authorization is issued for the E0467.



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The following oxygen and oxygen equipment HCPCS codes for individual items are included in the functionality of code E0467:

• HCPCS codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E0447, E1390, E1391, E1392, E1405, E1406 and K0738

Claims for any of the HCPCS codes listed above that are submitted on the same claim or that overlap any date(s) of service for E0467 is considered to be unbundling.

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service for any of the following scenarios are considered as a claim for same or similar equipment when the beneficiary:

- Is currently in a rental month for any of the items listed above
- Owns any of the equipment listed above that has not reached the end of its reasonable useful lifetime.
- Has oxygen equipment that reached the 36-month rental but has not reached the end of its reasonable useful lifetime.

Current ventilator users that meet one of the equipment rental schedules below are eligible for the **multi-function ventilator**:

- Ventilator users that have used cough, suction, and nebulizer for less than 13 months
- Ventilator users that have used oxygen therapy for less than 36 months
- Ventilator users that own one of the rental items (or reached the 36-month cap for oxygen) but have exceeded the reasonable useful life of 5 years and are eligible for a new device.

Coverage of Second Ventilator

A second invasive or non-invasive ventilator may be considered reasonable and necessary if it is required to serve a different purpose as determined by the member's



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medical needs. Examples (not all-inclusive) of situations in which multiple ventilators may be considered reasonable and necessary are:

- An individual requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) for part of the day and needs a different type of ventilator (e.g., positive pressure ventilator with a nasal mask) during the rest of the day.
- An individual who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without both pieces of equipment, the individual may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively.

The following criteria is required for **ALL** home ventilators:

- Had a full evaluation to determine the need for a ventilator and the most appropriate type of ventilator, with a physician who is skilled in respiratory assisted ventilation and/or pulmonology medicine AND
- Has been evaluated for strategies to minimize ventilator use (weaning or partial weaning from the ventilator) including breathing techniques and diaphragmatic pacer devices.
- Family members must be adequately trained, with documentation of competency of the skills as determined by a return demonstration, prior to caring for the member in the home.
- Care should be taken to assure that the actual ventilator settings as seen on the control panel match the prescribed settings.
- Alarms and ventilator settings should be monitored to ensure member safety.
- Family/member should have access to a trained professional in respiratory care and ventilator management for technical and clinical support 24 hours a day.
- DME respiratory clinicians should visit patients at least monthly or per company policy.

Limitations



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- 1. Supplies used in conjunction with the ventilator (e.g., breathing circuits, A4618) are included in the monthly rental and are not separately payable.
- 2. Supplies are separately payable if the ventilator and the individual accessories are member owned and medically necessary.
- 3. Repair of a member owned ventilator is limited to restoration of a serviceable condition which is not the result from misuse, non-intentional or intentional.
- 4. The separate stand-alone rental devices and accessories that are integrated into the multi-function ventilator or which represent similar equipment used for the same purpose must be denied if billed in conjunction with the new multi-function ventilator.
- 5. An additional or duplicate home ventilator device (HCPCS E0465-E0466) is considered NOT medically necessary as a backup device (similar device as the individual's primary ventilator, for multiple residences or to have in case of possible malfunction).
- 6. A home ventilator device (HCPCS E0465-E0466) is considered NOT medically necessary for any of the following:
 - A non-life-threatening condition
 - When the sole purpose of the home ventilator is to function as a respiratory assistance device (RAD) including continuous positive airway pressure (CPAP), auto-titrating PAP (APAP), bilevel positive airway pressure (BPAP, BiPAP) or adaptive servo-ventilation (ASV)
 - Treatment for obstructive sleep apnea

Note: Electrical generators do not meet the definition of DME because they are not primarily medical in nature.

HCPCS Level II Codes and Description

E0457	Chest shell (Cuirass)
E0459	Chest wrap
E0465	Home ventilator, any type, used with invasive interface (e.g., tracheostomy tube)
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.

Important Note:



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Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Northwood follows all CMS National coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

- National Coverage Determination (NCD) for Durable Medical Equipment (DME) Reference List (280.1).NCD CAG-00465N NCD - Durable Medical Equipment Reference List (280.1) Last accessed/reviewed 11-7-25.
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Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	11-20- 06	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01		Annual Review – no changes	Susan Glomb	Ken Fasse	Dec.2008	
02	12-22- 09	Annual Review- no changes	Susan Glomb	Ken Fasse	Dec.2009	
03	12-08- 10	Annual Review – No changes	Susan Glomb	Ken Fasse	Dec.2010	
04	07-20- 11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		



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05	12-08- 11	Annual Review. Added language regarding second ventilator criteria. Added References to Policy	Susan Glomb	Dr. B. Almasri	Dec. 2011	
06	04-03- 12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
07	11-30- 12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012	
08	12-18- 13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
09	11-25- 14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
10	11-25- 15	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	November 2015	
11	11-18- 16	Annual Review. Updated HCPCS codes.	Lisa Wojno	Dr. B. Almasri	November 2016	
12	11-17- 17	Annual review. Updated policy to reflect caregiver training and member/caregiver access to tech/clinical support 24 hour a day.	Carol Dimech	Dr. C. Lerchin	November 2017	
13	11-19- 18	Annual Review. No Changes.	Lisa Wojno	Dr. C. Lerchin	November 2018	
14	9-24- 19	Policy updated to reflect addition of HCPCS Code E0467 Multi-function ventilator.	Susan Glomb	Dr. C. Lerchin	September 2019	
15	11-14- 19	Annual review. No changes.	Lisa Wojno	Dr. C. Lerchin	November 2019	11-2019
16	11-30- 2020	Annual Review. Merged Non-Invasive Negative Pressure Ventilator policy information with Ventilator's policy.	Carol Dimech	Dr. C. Lerchin	November 2020	November 30, 2020
17	6-8-21	Defined E0465, E0466, E0467. Added National Coverage Determination criteria/diagnoses for E0465 and revised policy	Carol Dimech	Dr. C. Lerchin	7-7-21	7-7-21



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		for clarity. Added to criteria list/limitations for all home ventilators.				
18	11-29- 21	Annual Review. No changes since 6-8-21 refer to #17. Also added NCD/LCD verbiage to "Important Note".	Carol Dimech/Susan Glomb	Dr. C. Lerchin	November 2021	
19	11-17- 22	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-17-22	11-17-22
20	11-20- 23	Annual review. No changes	Susan Glomb	Dr. C. Lerchin	11-20-23	11-20-23
21	11-19- 24	Annual review. Updated references.	Carol Dimech	Dr. C. Lerchin	11-19-24	11-19-24
22	7-18- 25	Added current NCD criteria.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	7-18-25	7-18-25
23	11-7- 25	Annual review. No changes.	Lisa Wojno	Dr. C. Lerchin	11-7-25	11-7-25