Medical Coverage Policy

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Home Ventilators

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted

for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses in-home ventilators for children and adults (HCPCS E0466-E0468 only). Ventilators are rental only DME and require on-going rental period authorizations.

Coverage Policy

Coverage for Durable Medical Equipment (DME), including in-home ventilators varies across plans. Please refer to the customer's benefit plan document for coverage details.

NON-INVASIVE INTERFACE (HCPCS E0466)
A home ventilator with non-invasive interface (e.g., facemask) is considered medically necessary when ALL of the following criteria are met:

- Individual has ONE of the following AND lack of ventilator support would result in a life-threatening condition:
  - a neuromuscular disease
  - a thoracic restrictive disease
  - chronic respiratory failure consequent to chronic obstructive pulmonary disease
  - congenital central hypoventilation syndrome
  - chronic lung disease of infancy (e.g., bronchopulmonary dysplasia)
  - obesity hypoventilation syndrome
  - restrictive disorder of chest wall
- Individual has demonstrated failure of bilevel positive airway pressure (BPAP) to improve hypercapnia and/or oxygen saturation level
- Individual does not require ventilation continuously (24 hours/day)

CONTINUED USE
An in-home ventilator is considered medically necessary for continued use when all of the following criteria are met:

- the pretreatment clinical condition met initial criteria
- there is documentation of compliant usage

MULTI-FUNCTION (HCPCS E0467)
The Ventilation, Oxygen, Cough, Suction, Nebulization (VOCSN) multifunction ventilator is considered medically necessary for an individual who meets the medical necessity coverage criteria for a home ventilator AND has a requirement for MORE than one of the four additional functions (oxygen concentrator, cough stimulator, suction pump and nebulizer).

DUAL-FUNCTION (HCPCS E0468)
A dual-function ventilator (e.g., VOCSN VC, VOCSN VC Pro) is considered medically necessary for an individual who meets the medical necessity coverage criteria for a home ventilator AND has a requirement for cough stimulation.

ADDITIONAL OR DUPLICATE DEVICES

An additional home ventilator device (HCPCS E0466-E0468) is considered medically necessary for EITHER of the following conditions:

- **For mobility when all of the following criteria are met:**
  - the individual meets the medical necessity coverage criteria for the specified home ventilator
  - the individual requires mechanical ventilation during mobility (e.g., for use in wheelchair) as prescribed in their plan of care
  - the primary ventilator is not portable or not suitable for use with a wheelchair

- **In addition to negative pressure ventilator when both of the following criteria are met:**
  - the individual meets the medical necessity coverage criteria for the specified home ventilator
  - a negative pressure ventilator is required for part of the day and a positive pressure ventilator is necessary during the rest of the day, as prescribed in their plan of care

An additional or duplicate home ventilator device (HCPCS E0466-E0468) is considered NOT medically necessary as a back-up device (similar device as the individual's primary ventilator, for multiple residences or to have in case of possible malfunction).

NOT MEDICALLY NECESSARY

A home ventilator device (HCPCS E0466-E0468) 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), adaptive servo-ventilation (ASV), average volume assured pressure support (AVAPS), or intelligent volume assured pressure support (iVAPS)
- treatment for obstructive sleep apnea

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

A ventilator, also known as a respirator, can help a person breathe when they are unable to breathe sufficiently on their own. A mechanical ventilator can take over the act of breathing completely or make breathing easier by assisting weakened respiratory muscles. Mechanical ventilation is indicated in respiratory failure, which is defined as insufficient oxygenation,

insufficient alveolar ventilation, or both. The desired effect of mechanical ventilation is to maintain appropriate levels of Po2 and Pco2 in arterial blood while unloading the ventilatory muscles. Ventilators can be classified as either invasive or non-invasive. Invasive ventilators use an endotracheal tube or tracheostomy tube to deliver oxygen to the patient. Non-invasive ventilators use nasal masks, oral masks, nasal pillows, or a full-face mask to deliver oxygen to the patient.

Positive Pressure Ventilation
The majority of all mechanical ventilatory support is provided by positive pressure ventilation. Positive pressure ventilators developed as a more effective breathing option to the larger, bulkier negative pressure devices (e.g., iron lung). Since the 1980s, computer technology has enabled manufacturers to produce even smaller, lightweight ventilators that are easier to transport and operate, and are better suited for people living at home. Home ventilators may be used via:

- an invasive interface (i.e., tracheostomy) or
- a non-invasive interface (i.e., nose or mouth mask, chest shell).

After careful evaluation and pulmonary function tests to assess breathing and lung function and capacity, the physician recommends a type of ventilator and appropriate interfaces. In the USA, physicians work with respiratory therapists in home health care companies that provide the equipment, supplies, and education, training and monitoring. Individuals who need to use ventilation only at night have different equipment requirements than those who need to use a ventilator around the clock. Sometimes an individual may not be comfortable with a specific ventilator or interface and may need to change them in order to find the most comfortable and effective system. Some ventilator users alternate modes and interfaces during the day and night. There are some clinical scenarios that warrant both a primary ventilator and a secondary ventilator. An example is if an individual requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) during the day and needs a different type of ventilator (e.g., positive pressure ventilator with a face mask) during the night.

Multi-mode ventilators can provide many modes of ventilation, such as pressure support, pressure control, volume control, assist/control, synchronized intermittent mandatory ventilation (SIMV), bilevel positive pressure (BiPAP, BPAP) or continuous positive airway pressure (CPAP). Examples include LTV® series (CareFusion BD), iVent 201® (GE Healthcare), VOCSN Unified Respiratory System (Ventec Life Systems, Inc.) (FDA, 2025).

Utilizing a home ventilator as a respiratory assist device (RAD) (e.g., continuous positive airway pressure (CPAP), auto-titrating PAP (APAP), bilevel positive airway pressure (BPAP, BiPAP), adaptive servo-ventilation (ASV), average volume assured pressure support (AVAPS), or intelligent volume assured pressure support (iVAPS)) is considered not medically necessary. Numerous RADs have received FDA approval and may include minimum weight and/or age requirements that vary by device.

Food and Drug Administration (FDA)
Numerous positive and negative pressure ventilators are FDA-approved (FDA, 2025). One such example is the Ventilation, Oxygen, Cough, Suction, Nebulization (VOCSN) Unified Respiratory System (Ventec Life Systems, Inc., Bothell, Washington USA) which received 510(k) approval on April 7, 2017. Also known as the Ventec One-Circuit™, VOCSN is a multifunction ventilator that can provide five therapies or a mix of therapies from a single device. Therapies provided by VOCSN include: critical care ventilation; 6 L/min oxygen concentrator; touch button cough; hospital grade suction and high-performance nebulizer. The VOCSN is intended to provide continuous or intermittent positive pressure ventilator support for the care of individuals who require mechanical ventilation. It may be used in invasive and non-invasive applications. The VOCSN is intended for pediatric through adult patients weighing at least 5 kg. It is intended for use in home, hospital, institutional and transport settings, including portable applications. The integral oxygen

concentrator is intended for the administration of supplemental oxygen. The integral suction pump is intended for airway fluid removal and oral/ pharyngeal hygiene. The integral cough assist option is intended for patients who are additionally unable to cough or clear secretions effectively.

Utilizing the same FDA clearance as the VOCSN Unified Respiratory System, Ventec Life Systems' parent company, React Health, has marketed the VOCSN VC and VOCSN VC Pro ventilators. These ventilators are like the VOCSN with the exception that they only combine two primary therapies: ventilation and cough stimulation.

Literature Review
The Agency for Healthcare Research and Quality (AHRQ) Technology Assessment on Non-invasive Positive Pressure Ventilation in the Home (Final report 2/04/2020) evaluated home non-invasive positive pressure ventilation (NIPPV) in adults with chronic respiratory failure in terms of initiation, continuation, effectiveness, adverse events, equipment parameters and required respiratory services. Devices evaluated were home mechanical ventilators (HMV), bi-level positive airway pressure (BPAP) devices, and continuous positive airway pressure (CPAP) devices.

Of the included 68 studies, 14 evaluated home mechanical ventilator (HMV). Key messages include:

- In patients with COPD, home NIPPV as delivered by a BPAP device (compared to no device) was associated with lower mortality, intubations, hospital admissions, but no change in quality of life (low to moderate strength of the body of evidence [SOE]). NIPPV as delivered by a HMV device (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions (low SOE). In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality (low SOE). In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life (low SOE). In patients with obesity hypoventilation syndrome, HMV/BPAP mix (compared to no device) was associated with lower mortality (low SOE). BPAP (compared to no device) was associated with improved sleep quality.
- Current evidence is insufficient to assess the comparative effectiveness of many NIPPV device capabilities on patient outcomes; particularly comparing HMV to BPAP. Future studies should address which device capabilities are associated with improved patient outcomes.
- Criteria to initiate home NIPPV and home respiratory services were summarized in this report but varied and were not validated in comparative studies.
- Incidence of non-serious adverse events such as facial rash, dry eyes, mucosal dryness, and mask discomfort across devices was approximately 0.3 events over a median duration of device used of 6 months. The most commonly reported serious adverse event was acute respiratory failure. Based on direct comparisons, we found no statistically significant differences in number of treatment withdrawals or adverse events when comparing different devices or when comparing device use with no device use.

Professional Societies/Organizations

American Thoracic Society (ATS): The ATS Clinical Practice Guideline, "Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome" (Fan, et al., 2017), is an evidence-based clinical practice guideline on the use of ventilatory strategies and associated cointerventions in adult patients with acute respiratory distress syndrome (ARDS), providing treatment recommendations on the basis of these interventions. It does NOT specifically address home setting or portable ventilation.

- The recommendations for the following interventions for the treatment of ARDS are strong:

- Mechanical ventilation using lower tidal volumes (4–8 ml/kg predicted body weight) and lower inspiratory pressures (plateau pressure,30 cm H2O) (moderate confidence in effect estimates)
- Prone positioning for more than 12 h/d in severe ARDS (moderate confidence in effect estimates)

- The recommendation against the following intervention for the treatment of ARDS is strong:
  - Routine use of high-frequency oscillatory ventilation in patients with moderate or severe ARDS (high confidence in effect estimates)

- The recommendation for the following interventions for the treatment of ARDS is conditional:
  - Higher positive end-expiratory pressure in patients with moderate or severe ARDS (moderate confidence in effect estimates)
  - Recruitment maneuvers in patients with moderate or severe ARDS (low confidence in effect estimates)

- Additional evidence is necessary to make a definitive recommendation for or against the use of extracorporeal membrane oxygenation in patients with severe ARDS.

American Thoracic Society (ATS): The ERS/ATS Clinical Practice Guideline on the Management of COPD Exacerbations (Wedzicha, et al., 2017) notes the following:

- For hospitalized patients with acute or acute-on-chronic hypercapnic respiratory failure due to a COPD exacerbation, we recommend the use of NIV (strong recommendation, low quality of evidence).
- For patients with a COPD exacerbation who present to the emergency department or hospital, we suggest a home-based management program (hospital-at-home; conditional recommendation, moderate quality of evidence).

American Academy of Neurology (AAN): The AAN provides the following recommendations in their practice parameter update on the care of the patient with Amyotrophic Lateral Sclerosis (Miller, et al., 2009; Reaffirmed on Feb 25, 2023):

Respiratory Management
- Nocturnal oximetry may be considered to detect hypoventilation (regardless of the forced vital capacity, FVC) (Level C*).
- Supine FVC and maximal inspiratory pressure (MIP) may be considered useful in routine respiratory monitoring, in addition to the erect FVC (Level C).
- Sniff nasal pressure (SNP) may be considered to detect hypercapnia and nocturnal hypoxemia (Level C).
- Noninvasive ventilation (NIV) may be considered to enhance quality of life (QOL) in patients with ALS who have respiratory insufficiency (Level C).
- Tracheostomy invasive ventilation (TIV) may be considered to preserve QOL in patients with ALS who want long-term ventilator support (Level C).
- NIV may be considered at the earliest sign of nocturnal hypoventilation or respiratory insufficiency in order to improve compliance with NIV in patients with ALS (Level C).
- Mechanical insufflation/exsufflation (MIE) may be considered to clear secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection (Level C).
- There are insufficient data to support or refute high frequency chest wall oscillation (HFCWO) for clearing airway secretions in patients with ALS (Level U*).

Recommendations for Future Research:

- Evaluate SNP as a criterion for NIV initiation.
- Evaluate the impact of early NIV initiation on survival and quality of life.
- Assess the impact of executive dysfunction on NIV compliance.
- Evaluate the effect of hypoventilation on executive dysfunction.
- Compare techniques for clearing upper airway secretions at various stages of respiratory and bulbar dysfunction.
- Evaluate pulmonary tests, compliance with NIV, and outcomes in patients with bulbar dysfunction.

  * C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)
  U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

American Academy of Neurology (AAN) Consensus-based care recommendations for adults with myotonic dystrophy type 1: The AAN care recommendations (Ashizawa, et al., 2018) note the following:

- Under section Life threatening symptoms—Clinical care recommendations
  - Vaccinate for pneumonia and flu; treat respiratory infections quickly and use cough assistance and mechanical ventilation as needed along with obtaining consultations from respiratory therapy and pulmonary medicine groups.
  - Some patients will eventually require either nighttime ventilator support or full-time ventilation. Most patients with chronic respiratory insufficiency respond to noninvasive ventilatory support (NIV). Patients experiencing acute respiratory failure require endotracheal intubation with positive pressure ventilation.
  - For chronic respiratory insufficiency, use supplemental oxygen with caution and in conjunction with NIV (see Surgery, anesthesia, and pain).
  - If surgery is planned, reassess clearance capacity if needed, possible adaptation to NIV or cough assistance.

- Under section re Excessive daytime sleepiness (EDS) symptoms:
  - If nocturnal or daytime hypoventilation is suspected, consider noninvasive positive pressure ventilation, and refer to a pulmonologist with experience in neuromuscular diseases re: possible need for NIV launching.

- Under Pregnancy / Obstetrical management:
  - Include a pediatric or neonatal specialist present at delivery; intensive neonatal care is recommended for neonates that may have DM1; anticipate need for feeding tube and ventilator support (recommended even if the fetus is known to be unaffected).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Durable Medical Equipment (280.1)	5/5/2005
LCD	CGS	Respiratory Assist Devices (L33800)	1/1/2024

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0466	Home ventilator, any type, used with non-invasive 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
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions

References

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3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Mar 27, 2025. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

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5. Fan E, Del Sorbo L, Goligher EC, Hodgson CL, Munshi L, American Thoracic Society, European Society of Intensive Care Medicine, and Society of Critical Care Medicine, et al.

An Official American Thoracic Society/European Society of Intensive Care Medicine/Society of Critical Care Medicine Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med. 2017 May 1;195(9):1253-1263. Erratum in Am J Respir Crit Care Med. 2017 Jun 1;195(11):1540. Accessed Mar 27, 2025. Available at URL address: https://www.thoracic.org/statements/cc.php

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7. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification. Page last updated: Mar 24, 2025. Product code CBK. Access Mar 27, 2025. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

8. Wedzicha JA, Miravitlles M, Hurst JR, Calverley PMA, Albert RK, Anzueto A, et al. Management of COPD exacerbations: an ERS/ATS guideline. Eur Respir J 2017; 49:1600791.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Removed the policy statement for an invasive interface.	6/15/2025
Annual Review	Added a policy statement for the VOCSN VC and VOCSN VC Pro ventilators.	6/15/2024