09-E0000-55

Original Effective Date: 05/15/16

Reviewed: 05/22/25

Revised: 06/15/25

Subject: Positive Pressure Ventilation (Invasive and Noninvasive)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

The main function of the respiratory system is to get oxygen into the body and to remove carbon dioxide. When a patient's lungs are no longer able to adequately perform this function mechanical ventilation is used. Chronic respiratory failure is defined as the long-term inability to maintain oxygen and carbon dioxide levels within normal limits. Many disease conditions may lead to chronic respiratory failure including, but not limited to neuromuscular diseases, thoracic restrictive diseases (including thoracic cage abnormalities and morbid obesity), chronic obstructive pulmonary disease, and hypoventilation syndromes such as obesity hypoventilation. Conditions such as these may be relatively stable over time or progressive in nature. Chronic respiratory failure is a common condition that may require long-term home mechanical ventilation.

Noninvasive ventilation differs from invasive ventilation (E0465) using an invasive interface between the patient and ventilator. In the home setting invasive ventilator support is provided via tracheostomy tube. Noninvasive ventilator support uses interfaces such as nasal masks; orofacial masks mouthpieces, nasal pillows, or full-face mask.

In 2017, the VOCSN Unified Respiratory System (Ventec Life Systems, Inc.) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation. It is a Class II continuous ventilator and 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; and the integral cough assist option is intended for patients who are additionally unable to cough or clear secretions effectively.

POSITION STATEMENT:

Note: This guideline does not address the use of other respiratory assist devices including BiPAP or CPAP. Positive pressure ventilators can be set up to function in a bi-level mode, and should not be provided when a bi-level device with and without back up meets the member's needs.

Mechanical ventilation is intended for adult and infant patients weighing at least 5 kg (Il I bs) with tidal volumes of at least 50ml and may be used for both invasive and non-invasive ventilation.

Indications for Non-Invasive Positive Pressure Ventilation (E0466)

Non-invasive positive pressure ventilation (NPPV) **meets the definition of medical necessity** when criteria below are met (1-5):

1. The physician documentation in the medical record includes objective evidence that:
    - the member is in chronic respiratory failure and the member's condition is so severe that management with a bi-level device with pressure support is not possible (i.e. CO2 and O2 levels could not be adequately corrected, a low or fluctuating tidal volume requires more precise monitoring and volume settings that cannot be accomplished with a bi-level device with back up)
2. Treatment of **ONE** of the following respiratory insufficiency conditions **(A, B, C, or D):**
    A. Thoracic restrictive lung disease with any of the following:
        - PaCO2>45mmHg
        - FVC<40% normal
        - MIP<60cmH2O
        - Nocturnal SaO2<88% for ≥5 consecutive minutes, done while breathing the member's usual FiO2.

    B. Chronic obstructive pulmonary disease (COPD) when the member meets at least one of the following criteria:
        - PaCO2 greater than or equal to 56mmHg; **OR**
        - Higher pressure (e.g. > 25 cm H2O) is needed to reduce hypercapnia than can be achieved with a bi-level device during titration; **OR**
        - Severe hypoxemia requiring FiO2 > 40% or > 5 L/min; **OR**
        - Daytime use (battery operated unit) is required to reduce hypercapnia.

    Note: For members with COPD without hypercapnia (PaCO2 < 52 mmHg) and with obstructive sleep apnea, see Positive Airway Pressure Devices policy.

    C. Progressive Neuromuscular Disease with respiratory failure with any of the following:
        - PaCO2>45mmHg

- FVC<50%
- MIP <60cmH2O
- Nocturnal SaO2 < 88% for ≥5 consecutive minutes, done while breathing the member's usual FiO2.

For example:

- ALS
- Hereditary progressive muscular dystrophy
- Multiple Sclerosis
- Spinal muscle atrophy unspecified
- Myasthenia gravis without acute exacerbation
- Myotonic muscular dystrophy
- Primary lateral sclerosis.

D. Central hypoventilation syndrome or obesity hypoventilation with PaCO2 >45mmHg and pH>7.35.

3. Member has had optimal medical therapy for underlying respiratory disorders **AND**

4. Member (or caregiver) is able to protect airway and clear secretions adequately **AND**

5. Member's reversible contributing factors have been treated (e.g., obstructive sleep apnea, hypothyroidism, congestive heart failure, severe electrolyte disturbance).

Pediatric Indications for Non-Invasive Positive Pressure Ventilation

Non-invasive positive pressure ventilation (NPPV) **meets the definition of medical necessity** for children of all ages when all criteria below are met:

1. Discharged from hospital on a ventilator and there is physician documentation to support medical necessity. **AND**
2. Conditions that affect normal respiratory balance (eg, those associated with dysfunction of the central drive or respiratory muscles) and disorders characterized by an increase in respiratory load (eg, obstructive airway or lung diseases). Condition categories include but aren't limited to:
    - Chronic respiratory failure
    - Bronchopulmonary Dysplasia of prematurity
    - Acute respiratory infection caused by COVID (ARDS)
    - Myopathic disorders
    - Congenital central hypoventilation syndrome
    - Chest wall disorder

- Cystic Fibrosis
- Pulmonary hypertension
- Diaphragmatic paralysis

AND

3. Member (or caregiver) is able to protect airway and clear secretions adequately.

Indications for Invasive Positive Pressure Ventilation (E0465)

Invasive ventilation **meets the definition of medical necessity** when:

1. The member meets criteria for non-invasive ventilation, and
2. The member has a condition or their condition has progressed such that they have persistent symptomatic respiratory failure that can no longer be corrected with a noninvasive interface.

Continued Need of Invasive and Non-Invasive Positive Pressure Ventilation for all members

Clinical documentation by the treating physician within the previous 12 months is required to support the medical necessity for ongoing invasive or non-invasive positive pressure ventilation.

Multi-Use Ventilators (VOCSN) (E0467, E0468)

A multi-use ventilator **meets the definition of medical necessity** for members new to home mechanical ventilation who meet criteria for a home ventilator and diagnosed with neuromuscular diseases, thoracic restrictive diseases, or chronic respiratory failure consequent to chronic obstructive pulmonary disease.

(See Billing/Coding Information section below for additional information)

Second Ventilators and Back up Ventilators

A second ventilator **meets the definition of medical necessity** if it is required to serve a different purpose than the primary ventilator, as determined by the member's medical needs. (e.g. A member 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 two pieces of equipment, the member 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.)

NOTE: A second ventilator must be distinguished from a back-up ventilator. A back-up ventilator is defined as an identical or similar device used to meet the same medical needs for the member but provided at the bedside as a precaution in case of malfunction of the primary ventilator. The member's Durable Medical Equipment (DME) provider is responsible for ensuring that the member's medical needs will be met on a continuous and ongoing basis.

Use of positive pressure ventilators for all other indications **does not meet the definition of medical necessity** including:

- Treatment of obstructive sleep apnea, even though the ventilator equipment may have the capability of operating in a CPAP (E0601) or bi-level PAP (E0470) mode (clinical outcomes has not been shown to be superior to other standard treatments (e.g., CPAP, BiPAP));
- Treatment of a condition with a non-invasive positive pressure ventilator that can be managed by an E0470/E0471 and would preclude the use of an E0466 when basic PAP could be equally efficacious
- Clinical conditions that require bi-level functionality for intermittent and relatively short durations of respiratory support would not be appropriate for a positive pressure ventilator (E0466) even though the ventilator equipment may have the capability of operating in a bi-level PAP mode.

BILLING/CODING INFORMATION:

HCPCS Coding

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
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions

Ventilator technology has evolved to the point where it is possible to have a single device capable of operating in numerous modes, from basic continuous positive pressure (CPAP) and bi-level positive airway pressure (Bi-PAP) to traditional pressure and volume ventilator modes. This creates the possibility that one piece of equipment may be able to replace numerous and different pieces of equipment. Equipment with multifunction capability creates the possibility of errors in claims submitted for these items. General principles of correct coding require that products assigned to a specific HCPCS code only be billed using the assigned code. Thus, using the HCPCS codes for CPAP (E0601) or bi-level PAP (E0470/E0471) devices for a ventilator (E0466) used to provide CPAP or bi-level PAP therapy is incorrect coding. Claims for ventilators billed using the CPAP or bi-level PAP device HCPCS codes will be denied as incorrect coding.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Durable Medical Equipment Reference List (280.1), located at cms.gov.

The following was reviewed on the last guideline reviewed date and are located at cgsmedicare.com: Correct Billing and Coding of Ventilators; Local Coverage Article Respiratory Assist Devices - Policy Article (A52517); Local Coverage Determination (LCD) Respiratory Assist Devices (L33800).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Oxygen, 09-E0400-00

Positive Airway Pressure Devices, 09-E0000-21

OTHER:

REGULATORY STATUS: In April 2017, the FDA approved the VOCSN Unified Respiratory System, by Ventec Life Systems, Inc. The device is a Class II continuous ventilator. VOCSN integrates five separate devices including a ventilator, oxygen concentrator, cough assist, suction, and nebulizer into one unified respiratory system. The VOCSN FDA-approved indication for use is to provide continuous or intermittent 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.

REFERENCES:

1. Agency for Healthcare Research and Quality Comparative Effectiveness Review Number 68, Noninvasive Positive-Pressure Ventilation (NPPV) for Acute Respiratory Failure, accessed at effectivehealthcare.ahrq.gov.
2. Agency for Healthcare Research and Quality Noninvasive Positive Pressure Ventilation in the Home Final Technology Assessment Project ID: PULT0717 2/4/2020, accessed at ahrq.gov.
3. Agency for Healthcare Research and Quality Evidence-based Practice Center Systematic Review Protocol Project Title: Home Mechanical Ventilators Project ID: PULT0717 Initial publication date: February 2, 2018 accessed at ahrq.gov.
4. Agency for Healthcare Research and Quality, Project Title: Noninvasive Positive-Pressure Ventilation (NPPV) for Acute Respiratory Failure, April 21, 2011; accessed at ahrq.gov.

5. Blue Cross Blue Shield Association (BCBSA) Evidence Positioning System®. 8.01.64, Non-Invasive Positive Airway Pressure; 04/25.
6. Branson R, Dichter JR, et al. The US Strategic National Stockpile Ventilators in Coronavirus Disease 2019: A Comparison of Functionality and Analysis Regarding the Emergency Purchase of 200,000 Devices. Chest. 2021 Feb;159(2):634-652.
7. Centers for Medicare & Medicaid Services (CMS). Medicare Learning Network. MLN Matters MM10854 Implementation of a Bundled Payment for MultiComponent Durable Medical Equipment (DME); accessed at cms.gov.
8. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1), accessed at cms.gov.
9. CGS Administrators, LLC. Correct Billing and Coding of Ventilators; accessed at cgsmedicare.com.
10. CGS Administrators, LLC. Local Coverage Article- Respiratory Assist Devices - Policy Article (A52517); accessed at cgsmedicare.com.
11. CGS Administrators, LLC. Local Coverage Determination (LCD)- Respiratory Assist Devices (L33800); accessed at cgsmedicare.com.
12. Hill NS, Criner GJ, Branson RD, et al. Optimal NIV Medicare Access Promotion: Patients With COPD: A 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. Chest. Nov 2021; 160(5): e389-e397. PMID: 34339684.
13. U.S. Food & Drug Administration (FDA); accessed at fda.gov.
14. Ventec Life Systems. Overview of Multi-Function Ventilator (E0476)- VOCSN; 2019.
15. Ventec Life Systems. VOCSN Multi-Function Ventilator Dossier, 2020.
16. Ventec Life Systems. VOCSN Research; located at venteclife.com.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 05/22/25.

GUIDELINE UPDATE INFORMATION:

05/15/16	New Medical Coverage Guideline.
12/15/16	Revision; description, position statement, and coding sections updated; formatting changes.
05/15/17	Annual review; guideline title, description, position statements, coding, and references updated.
04/15/19	Revision; Multi-use ventilator position statement added; description, coding, and references updated.
05/15/20	Review; Multi-use ventilator position statement maintained; policy title, description section, coverage criteria, and references updated.
12/15/20	Review; Non-invasive positive pressure ventilation position statements updated; all other position statements maintained; references updated.
07/15/21	Review; pediatric indications for non-invasive positive pressure ventilation position statements added; multi-use ventilator position statement maintained.

05/15/22	Revision: COPD criteria for non-invasive positive pressure ventilation updated; policy title and references updated.
11/15/23	Review: Coverage statement for multi-use ventilators added; coding and references updated.
04/01/24	Quarterly CPT/HCPCS update. Code E0468 added.
06/15/25	Review: Position statements maintained; program exceptions section and references updated.