

Noninvasive Ventilators in the Home Setting

Effective: September 1, 2023

Next Review: July 2024

Last Review: July 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Noninvasive ventilation (NIV) assistance or noninvasive positive pressure ventilation (NPPV) uses a nasal mask, face mask, or mouthpiece, connected to a ventilator to provide ventilation support during sleep or intermittently throughout the day.

MEDICAL POLICY CRITERIA

Notes: This policy only addresses home ventilators with a *noninvasive* interface (HCPCS code E0466). It does not address the use of other types of home ventilators, including those with an *invasive* interface (HCPCS E0465) or a multi-function home ventilator (HCPCS E0467).

- I. Use of a noninvasive ventilator in the home setting may be considered **medically necessary** when both of the following criteria are met (A. and B.):
 - A. The device is being requested to treat any of the following indications:
 1. Neuromuscular disease, or
 2. Thoracic restrictive disease, or

3. Chronic respiratory failure consequent to chronic obstructive pulmonary disease.
 - B. There is sufficient documentation in the medical record to support the condition is life-threatening where interruption of respiratory support would quickly lead to serious harm or death.
- II. Use of a noninvasive ventilator in the home setting is considered **not medically necessary** when Criterion I. is not met, including but not limited to the following situations:
 - A. The patient's condition is such that treatment may be adequately provided by a bilevel positive airway pressure device; or
 - B. Severity of the patient's condition is not severe and life-threatening.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

VENTILATOR WITH NOINVASIVE INTERFACES

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0465, E0466) are covered for the following conditions:^[1]

“[N]euromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These ventilator-related disease groups overlap conditions described in this Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

Ventilators fall under the Frequent and Substantial Servicing (FSS) payment category, and payment policy requirements preclude FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. (Social Security Act 1834(a)(3)(A)) This means that products currently classified as HCPCS code E0465 or E0466 when used to provide CPAP or bi-level PAP (with or without backup rate) therapy, regardless of the underlying medical condition, shall not be paid in the FSS payment category. A ventilator is not eligible for reimbursement for any of the conditions described in this RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Claims for ventilators used to provide CPAP or bi-level CPAP therapy for conditions described in this RAD policy will be denied as not reasonable and necessary.

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 (E0465, 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.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- All chart notes and medical records pertinent to the request (e.g., supporting documentation of neuromuscular disease, thoracic restrictive disease, and/or chronic respiratory failure consequent to COPD).
- Documentation must demonstrate that the condition is life-threatening where interruption of respiratory support would quickly lead to serious harm or death.

CROSS REFERENCES

1. [Phrenic Nerve Stimulation for Central Sleep Apnea](#), Surgery, Policy No. 212

BACKGROUND

This policy is based on the Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1; and Local Coverage Determination (LCD): Respiratory Assist Devices (L33800).^[1, 2]

NONINVASIVE VENTILATORS

Ventilators, also known as respirators, are medical devices used to mechanically assist with a patients' breathing. Mechanical ventilation is often categorized by the interface used, such as a tracheostomy tube for invasive ventilation, or a mask for non-invasive ventilation. Non-invasive ventilation (NIV) assistance or non-invasive positive pressure ventilation (NPPV) uses a nasal mask, face mask, or mouthpiece, connected to a ventilator to provide ventilation support during sleep or intermittently throughout the day. In the hospital setting, a trial of NPPV may be attempted prior to invasive treatment. Ventilation support rests the lung muscles and improves breathing performance during the day. At night, ventilation may be used to treat sleep-associated hypoventilation. If use is at night only, this is referred to as nocturnal NPPV. If use is intermittent, this may be referred to as "Mouthpiece" or "Sip and Puff" ventilation. Supplemental oxygen may also be added to this type of system.

In recent decades, NPPV has been used for treatment in the home setting. BPAP are portable pressure-limited ventilators, which are more commonly used than portable volume-limited ventilators. In some populations, efficacy is similar with both types of devices according to comparative studies, thus the portable pressure-limited ventilators are usually preferred over portable volume-limited ventilators, because of lower cost, better portability, and often greater comfort.^[3]

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved numerous portable home ventilators through the 510(k) process. A non-exhaustive list of examples includes the following:

- Servo-u Ventilator system 4.1 (Rontgenvagen)
- Trilogy™ (Philips Respironics)
- Newport® (Newport Medical Instruments)
- IVent (GE Healthcare)
- Puritan™ (Covidien)
- LTV® (Carefusion)

FDA Product Code: CBK.

SUMMARY

There is enough research to show that use of a noninvasive ventilator in the home setting improves health outcomes for patients with neuromuscular disease, thoracic restrictive disease, or chronic respiratory failure consequent to chronic obstructive pulmonary disease. Clinical guidelines based on research recommend noninvasive ventilators for use in the home setting for these populations. Therefore, the use of a noninvasive ventilator in the home setting may be considered medically necessary when policy criteria are met.

In all other situations, the use of a noninvasive ventilator in the home setting is not associated with improvements in health outcomes. Therefore, the use of a noninvasive ventilator in the home setting is considered not medically necessary when policy criteria are not met.

REFERENCES

1. U.S. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1). Version number: 2. Publication Number 100-3. Implementation Date 7/5/2005. [cited 07/24/2023]. 'Available from:' <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&ncdver=2&DocID=280.1&bc=gAAAABAAAA&>.
2. U.S. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Respiratory Assist Devices (L33800). For services performed on or after 01/01/2020. [cited 07/24/2023]. 'Available from:' <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33800&ver=26&Date=&DocID=L33800&bc=hAAAAAgAAA&=>.
3. Noridian Healthcare Solutions. Correct Coding and Coverage of Ventilators - Revised July 2020. [cited 07/24/2023]. 'Available from:' <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2020/correct-coding-and-coverage-of-ventilators-revised-july-2020>.

CODES

NOTE: Home ventilator codes requiring prior authorization are listed on the “Commercial Pre-authorization List” web page. Home ventilators not listed on the pre-authorization website do not require prior approval. There may be codes related to home ventilator systems that are not included in this medical policy.

Codes	Number	Description
CPT	None	
HCPCS	E0466	Home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell)

Date of Origin: July 2019