

## Clinical Policy: Home Ventilators

Reference Number: MC.CP.MP.184

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### Description

This policy describes medical necessity criteria for noninvasive and invasive home ventilators, which is intended to supplement the criteria in National Coverage Determination (NCD): Durable Medical Equipment Reference List, Ventilators (280.1) and Local Coverage Determination (LCD): Respiratory Assist Devices (L33800). The coverage (medical necessity) criteria in NCD 280.1 and LCD L33800 note groups of diagnoses that qualify for home ventilators but do not provide enough detailed criteria regarding the clinical scenarios in which noninvasive home ventilation would be beneficial to the member/enrollee to consistently determine medical necessity. Noninvasive ventilation (NIV) describes the administration of positive pressure to the lungs using interfaces such as, but not limited to, nasal masks, orofacial masks, full face masks, mouthpieces, nasal pillows, or helmets.<sup>1,2</sup> Invasive ventilatory support describes the administration of positive pressure to the lungs through an invasive interface, such as a tracheostomy tube or endotracheal tube.<sup>1</sup>

The below criteria are sourced from NCD: Durable Medical Equipment Reference List, Ventilators (280.1) and LCD: Respiratory Assist Devices (L33800), which are supported by the Agency for Healthcare Research and Quality (AHRQ) 2020 Technology Assessment for Noninvasive Positive Pressure Ventilation in the Home.<sup>4,5,9</sup> Because this criteria has been sourced from an independent review of the scientific literature by the AHRQ, the balance of benefits and risks of harm from this criteria has been determined to be favorable. Per the AHRQ, noninvasive positive pressure ventilation in the home when deemed feasible and safe, is preferred to ventilation delivered in other settings. Advantages of home ventilation include lower cost, greater independence, increased quality of life, decreased risk of infections, and reduced use of acute care facilities.<sup>9</sup> The feature that distinguishes the non-invasive home ventilator (NHV) from a BiPAP is the NHV's ability to deliver variable airway pressures within a preset range to reach a targeted volume of ventilation with each breath.<sup>10</sup> For patients whose needs have been shown to exceed the support that a BiPAP at optimal settings can provide, an NHV is the next reasonable step.<sup>10</sup> The criteria below consider individual patient factors to assess whether NHV represents the most beneficial treatment versus CPAP or BiPAP.

### Note:

- *This policy outlines the medically necessary indications for home ventilator use in members/enrollees with conditions related to restrictive thoracic disorders or neuromuscular diseases. Chronic obstructive pulmonary disease (COPD) is out of scope for this policy*
- *For criteria applicable to non-Medicare plans, please see CP.MP.184 Home Ventilators.*

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#### Policy/Criteria

- I.** It is the policy of Medicare health plans affiliated with Centene Corporation® that *initial use of noninvasive home ventilators* are **medically necessary** when meeting the following:
- A. Member/enrollee has documentation of a neuromuscular disease (ex. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (ex. post-thoracoplasty for tuberculosis or severe kyphoscoliosis) and one of the following taken while member/enrollee was stable (not in acute respiratory failure):<sup>4,5,9,10</sup>
    1. An arterial blood gas partial pressure of carbon dioxide (PaCO<sub>2</sub>) was measured while awake and breathing room air or on prescribed oxygen with a measurement of PaCO<sub>2</sub> ≥ 45 mm Hg;<sup>4,9</sup>
    2. Sleep oximetry demonstrates O<sub>2</sub> saturation ≤ 88% for at least five minutes while breathing prescribed O<sub>2</sub>;<sup>4,9</sup>If neuromuscular disease is present, maximal inspiratory pressure is < 60 cm H<sub>2</sub>O, or forced vital capacity is < 50% predicted;<sup>4,9</sup>
  - B. Documentation supports both of the following:
    1. Member/enrollee could not be appropriately treated with a respiratory assist device (RAD);<sup>4,5,10</sup>
    2. The non-invasive home ventilator will not be used to provide RAD or CPAP therapy (i.e. will be used to provide average volume assured pressure support);<sup>4,5,10</sup>
  - C. Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation.<sup>4</sup>
- II.** It is the policy of Health Plans affiliated with Centene Corporation that *continued use of noninvasive home ventilators* after the initial three-month certification period is **medically necessary** when all of the following are documented:
- A. The device is used for at least an average of four hours per 24-hour period;<sup>5</sup>
  - B. Documentation supports both of the following:
    1. Ongoing benefits from use of the device;<sup>5,10</sup>
    2. The noninvasive home ventilator is not being used provide RAD or CPAP therapy (i.e. will be used to provide average volume assured pressure support).<sup>4,5,10</sup>
- III.** It is the policy of Health Plans affiliated with Centene Corporation that *noninvasive home ventilators for overlap syndromes* (presence of more than one condition) require **secondary review** by a medical director.<sup>4,10</sup>
- IV.** It is the policy of Health Plans affiliated with Centene Corporation that *initial and ongoing use of an invasive ventilator* is **medically necessary** for a long-term/chronic condition or disease affecting the ability to effectively maintain an adequate respiratory status. Examples of conditions may include neuromuscular disease or thoracic restrictive disease<sup>5</sup>
- V.** It is the policy of Health Plans affiliated with Centene Corporation that *a second or back up noninvasive or invasive ventilator* is considered **medically necessary** for the following indications:
- A. A second ventilator to serve a different purpose from the first ventilator, based on medical needs. (e.g., two different types of ventilators are needed for each day, e.g., negative pressure ventilator with chest shell for one indication and a positive pressure ventilator with nasal mask the rest of the day);<sup>11</sup>
  - B. A back-up ventilator for one of the following:
    1. Member/enrollee is confined to a wheelchair and requires a wheel-chair mounted ventilator during the day and another ventilator of the same type for use while in bed

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(unable to position the wheelchair-mounted ventilator close enough to the bed for use while sleeping). Without both pieces of equipment, member/enrollee may be prone to medical complications, unable to achieve appropriate medical outcomes, or may not be able to use the equipment effectively;<sup>11</sup>

2. Residence in remote areas with poor emergency access.

**Background**

The term respiratory failure refers to the inability to adequately perform the fundamental functions of respiration, delivery of oxygen to the blood stream and removal of carbon dioxide. Respiratory failure has many causes and can be acute or chronic in nature. Typically, respiratory failure initially affects the ability to effectively move oxygen into the body, also known as oxygenation failure, or to eliminate carbon dioxide, also known as ventilatory failure.<sup>2,6</sup>

Routine use of noninvasive ventilation has increased over the previous two decades, and as a result, noninvasive ventilation has become an essential tool in the management of acute and chronic respiratory failure in both the home and critical care settings.<sup>1</sup> Noninvasive ventilation offers increased flexibility and has become a valuable treatment option for patients with acidosis in moderate to severe respiratory distress and tachypnea with increased labored breathing due to COPD (chronic obstructive pulmonary disease) exacerbation.<sup>1,6</sup>

Ventilatory support is achieved through a variety of interfaces such as oronasal mask, nasal mask, nasal prongs or full-face mask and by using a variety of ventilatory modes (e.g., volume ventilation, pressure support, cuirass ventilation, bi-level positive airway pressure [BiPAP], proportional-assist ventilation [PAV], continuous positive airway pressure [CPAP]). Oxygen is delivered via tubing through a positive pressure ventilator circuit and should be heated and humidified to improve tolerance and prevent mucosal dryness, a common side effect of prolonged noninvasive ventilation. The primary goals of home noninvasive ventilation are reduction of symptoms, improvement of quality of life, reduced readmission risk and reduction of mortality.<sup>1,2,3</sup>

Invasive mechanical ventilation is primarily used to facilitate the exchange of oxygen and carbon dioxide, fully or partially, in patients with respiratory failure who no longer have the capacity to breathe spontaneously or whose ventilatory needs exceed their own ability to do so adequately. It is beneficial for protecting the airway of patients with a decreased level of consciousness, upper gastrointestinal hemorrhage, emesis, or other conditions with an increased risk of aspiration in whom noninvasive ventilation is contraindicated.<sup>7,8</sup>

**Coding Implications**

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HCPCS Codes	Description
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**Home Ventilators**

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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New policy.	02/24	02/24
Annual review. CPT code E0468 added. References reviewed and updated.	03/25	03/25
Policy description updated to note that the applicable NCD and LCD do not provide sufficient coverage criteria to consistently determine medical necessity, and note that the AHRQ evidence review independently considers scientific literature, as well as removing CMS LCDs as a factor for the benefits of the criteria.	12/25	
Annual review. Added note under Description to state that COPD is out of scope for this policy. Reformatted entire criteria I. to support removal of previous criteria I.B. regarding chronic respiratory failure due to COPD. Removed example of chronic respiratory failure following COPD from Criteria IV. Coding and descriptions reviewed. References reviewed and updated. Reviewed by external specialist.	02/26	02/26

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### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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