

Clinical Policy: Home Ventilators

Reference Number: CP.MP.184

Date of Last Revision: 05/24

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Description

This policy describes medical necessity criteria for noninvasive and invasive home ventilators. 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.^{1,2} Invasive ventilatory support describes the administration of positive pressure to the lungs through an invasive interface, such as a tracheostomy tube or endotracheal tube.¹

Note: For criteria applicable to Medicare plans, please see MC.CP.MP.184 Home Ventilators.

Policy/Criteria

- I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that **noninvasive home ventilators are medically necessary** for the following indications:
 - A. Initial request for the first three months of noninvasive home ventilator use for restrictive thoracic disorders, all of the following:^{4,5,9}
 1. 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):^{4,5,9,10}
 - a. An arterial blood gas partial pressure of carbon dioxide (PaCO₂) was measured while awake and breathing room air or on prescribed oxygen with a measurement of PaCO₂ ≥ 45 mm Hg;^{4,9}
 - b. Sleep oximetry demonstrates O₂ saturation ≤ 88% for at least five minutes while breathing prescribed O₂;^{4,9}
 - c. If neuromuscular disease is present maximal inspiratory pressure is < 60 cm H₂O, or forced vital capacity is < 50% predicted;^{4,9}
 2. Documentation supports both of the following:
 - a. Member/enrollee could not be appropriately treated with a respiratory assist device (RAD);^{4,5,10}
 - b. 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);^{4,5,10}
 3. Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation;⁴
 - B. Initial request for the first three months of noninvasive home ventilator use for severe COPD, all of the following:
 1. An arterial blood gas PaCO₂ measurement was done while awake and breathing at baseline and prescribed FIO₂ is ≥ 52 mm Hg;⁴

2. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if the medical record demonstrates that sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) is not the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation);⁴
 3. Documentation supports both of the following:
 - a. Member/enrollee could not be appropriately treated with a respiratory assist device (RAD);^{4,5,10}
 - b. 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);^{4,5,10}
- C. Initial request for the first three months of noninvasive home ventilator use for obesity hypoventilation syndrome (OHS) (also known as Pickwickian syndrome), all of the following:
1. BMI ≥ 30 ;^{13,14}
 2. An initial arterial blood gas PaCO₂, done while awake and breathing at baseline and the prescribed FIO₂ is ≥ 45 mm Hg;^{13,14}
 3. Sleep-disordered hypoventilation has been documented by polysomnography and other conditions are not considered the primary cause of hypoventilation (ex. lung parenchymal or airway disease, chest wall disorder (other than mass loading from obesity), medication use, neurologic disorder, muscle weakness, or a known congenital or idiopathic central alveolar hypoventilation syndrome);^{13,14}
 4. Documentation supports both of the following:
 - a. Member/enrollee could not be appropriately treated with a respiratory assist device (RAD);^{4,5,10}
 - b. 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);^{4,5,10}
- II.** It is the policy of non-Medicare Health Plans affiliated with Centene Corporation that ***continued use of noninvasive home ventilators*** after the initial three-month certification period is **medically necessary** when meeting the following:
- A. The device is used for at least an average of four hours per 24-hour period;⁵
 - B. Documentation supports both of the following:
 1. Ongoing benefits from use of the device;^{5,10}
 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).^{4,5,10}
- III.** It is the policy of non-Medicare Health Plans affiliated with Centene Corporation that ***noninvasive home ventilators for overlap syndromes*** (presence of more than one condition, such as COPD and sleep apnea) require **secondary review** by a medical director.^{4,10}
- IV.** It is the policy of non-Medicare 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, thoracic restrictive disease, or chronic respiratory failure following COPD.⁵

- V. It is the policy of non-Medicare 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, such as, a negative pressure ventilator with chest shell for one indication and a positive pressure ventilator with nasal mask the rest of the day);¹¹
 - 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 (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;¹¹
 - 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.^{2,15}

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.¹ 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.^{1,15}

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.^{1,2,3}

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.^{16,17}

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
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)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date (WellCare)	5/19	5/19
Annual review. Converted to new template. Clarified initial request is for 3 months. Applied contraindications to each indication. Removed verbiage about pediatric indications being addressed by state requirements. Removed requirements in the obesity hypoventilation syndrome indication for PSG or home sleep test demonstrating $\leq 88\%$ O2 saturation. Reworded statement about medical director review of overlap syndromes. Removed coding instructions related to billing of secondary codes, Medicare billing, and excluded codes. Updated background.	4/20	4/20
Added criteria for second/back up noninvasive ventilator from CP.MP.107 DME.	5/20	05/20
Removed code E0467. Replaced all instances of “member” with “member/enrollee,” or removed them where possible.	10/20	
References reviewed and updated. ICD-10 codes removed.	04/21	05/21
Annual review. Changed policy title from “Noninvasive Home Ventilators” to “Home Ventilators”. Removed (-) before 60 in I.A.1.b. Changed ≥ 45 to > 45 in I.A.1.a.i. Added pediatric criteria in I.A.1.a.ii. Changed I.A.1.b.i to apply to those over age 18 and added “1.A.1.b.ii. “For those < 18 years of age, documentation of Type 1 (hypoxemic) and/or Type 2 (hypercapnic) respiratory failure or inability to maintain airflow”. Replaced “tachypnea (respirations >24)” with “including tachypnea, increased work of breathing, hypoxemia, hypercapnia and/or	06/22	06/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
<p>respiratory acidosis (e.g., pH <7.35)” in I.A.2.c.; I.B.3.c.; I.C.3.c.; and I.D.1.c. Added “Baseline” to all “FIO₂ requirement > 0.40”. Moved invasive ventilator criteria from CP.MP.107 DME and placed in criteria IV. Combined invasive and noninvasive backup or second home ventilator into section V. Added HCPCS code E0465. Description and background updated to include information re: invasive ventilators. Reworded some extraneous language with no clinical significance. Changed “Review Date” in the header to “Date of Last Revision” and “Date” in the revision log header to “Revision Date.” References reviewed and updated. Specialist reviewed.</p>		
<p>Annual review completed. Minor rewording with no clinical significance. Background updated with no clinical significance. References reviewed and updated.</p>	06/23	06/23
<p>Annual review. Added note for corresponding Medicare policy. Updated all policy statements to indicate "non-Medicare" health plans. In I.A.1 changed "both" to "one" of the following and added "taken while member/enrollee was stable (not in acute respiratory failure)". Removed criteria for BiPAP failure and contraindications in sections I and II, and replaced with criteria requiring documentation that "member/enrollee could not be appropriately treated with a RAD" and "non-invasive home ventilator will not be used to provide RAD or CPAP therapy...". Removed criteria in I.A.1.a. and b. for members/enrollees < 18 years. In 1.A.1a. updated PaCO₂ > to greater than or equal to. In I.C.1 updated BMI > than 30 to greater than or equal to 30. In I.C.2 added "at baseline". Added criteria I.C.3. "Hypoventilation has been documented by polysomnography and other conditions are not considered the primary cause of hypoventilation..." Removed medical necessity criteria I.D. for home ventilators for treatment failure of BiPAP. In II.B. replaced "medical records document improvement..." with II.B.1. and 2. "Documentation supports: Ongoing benefits... and "non-invasive home ventilator will not be used to provide RAD or CPAP therapy...". Minor rewording throughout policy with no clinical significance. References reviewed and updated. External specialist review.</p>	05/24	05/24

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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

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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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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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