Clinical Policy: Home Ventilators

Reference Number: CP.MP.184
Date of Last Revision: 06/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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]

Policy/Criteria

I. It is the policy of 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:
   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 both of the following:
      a. One of the following:
         i. 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;
         ii. Sleep oximetry demonstrates O2 saturation of one of the following for at least 5 minutes while breathing prescribed O2:
            a. ≤88% for members/enrollees ≥ 18 years of age;
            b. <92% for members/enrollees < 18 years of age;
      b. If neuromuscular disease is present, one of the following:
         i. For those ≥ 18 years of age, maximal inspiratory pressure is < 60 cm H20, or forced vital capacity is < 50% predicted;
         ii. For those < 18 years of age, documentation of Type 1 (hypoxemic) and/or Type 2 (hypercapneic) respiratory failure or inability to maintain airflow.
   2. Respiratory failure has failed to improve with an adequate trial of bilevel positive airway pressure (Bi-PAP), as evidenced by one of the following: (Note: $PaCO_2$ levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize $PaCO_2$ levels alone is not considered a therapeutic failure of Bi-PAP)
      a. Intolerance to Bi-PAP, as indicated by the member's/enrollee's request to discontinue nocturnal assisted ventilation;
      b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia;
      c. Signs of respiratory failure, including tachypnea, increased work of breathing, hypoxemia, hypercapnia and/or respiratory acidosis (e.g., pH <7.35);
   3. Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation;

4. None of the following contraindications:
   a. Baseline FIO_2 requirement > 0.40;
   b. Positive-end expiratory pressure (PEEP) > 10 cm H_2O;
   c. Need for continuous invasive monitoring in adult patients**.**

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 $PaCO_2$ measurement was done while awake and breathing at baseline and prescribed FIO_2, which is greater than or equal to 52 mm Hg;
   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);
   3. Respiratory failure has failed to improve with an adequate trial of Bi-PAP, as evidenced by one of the following: (Note: $PaCO_2$ levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize $PaCO_2$ levels alone is not considered a therapeutic failure of Bi-PAP);
      a. Intolerance to Bi-PAP, as indicated by the member's/enrollee's request to discontinue nocturnal assisted ventilation;
      b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia;
      c. Signs of respiratory failure, including tachypnea, increased work of breathing, hypoxemia, hypercapnia and/or respiratory acidosis (e.g., pH <7.35);
   4. None of the following contraindications:
      a. Baseline FIO_2 requirement > 0.40;
      b. PEEP > 10 cm H_2O;
      c. Need for continuous invasive monitoring.

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 greater than 30;
   2. An initial arterial blood gas $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2, is ≥ 45 mm Hg;
   3. Signs of respiratory failure have failed to improve with an adequate trial of Bi-PAP as evidenced by one of the following: (Note: PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize $PaCO_2$ levels alone is not considered a therapeutic failure of Bi-PAP);
      a. Intolerance to Bi-PAP, as indicated by the member's/enrollee's request to discontinue nocturnal assisted ventilation;
      b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia;
      c. Signs of respiratory failure, including tachypnea, increased work of breathing, hypoxemia, hypercapnia, and/or respiratory acidosis (e.g., pH <7.35).
      d. An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO_2, shows the beneficiary's $PaCO_2$

worsened greater than or equal to 7 mm Hg compared to the original result (see C.2);

4. None of the following contraindications:
   a. Baseline FIO_2 requirement > 0.40;
   b. PEEP > 10 cm H_2O;
   c. Need for continuous invasive monitoring.

D. Initial request for the first three months of noninvasive home ventilator use for members/enrollees who have experienced treatment failure with Bi-PAP, both of the following:
   1. Treatment failure, one of the following:
      a. Intolerance to Bi-PAP, as indicated by member/enrollee request to discontinue nocturnal assisted ventilation;
      b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia;
      c. Signs of respiratory failure including tachypnea, increased work of breathing, hypoxemia, hypercapnia and/or respiratory acidosis (e.g., pH <7.35); (PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize $PaCO_2$ levels alone is not considered a therapeutic failure of Bi-PAP);
   2. None of the following contraindications:
      a. Baseline FIO_2 requirement > 0.40;
      b. PEEP > 10 cm H_2O;
      c. Need for continuous invasive monitoring.

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 meeting the following:
A. Medical records document improvement in relevant signs or symptoms due to the device;
B. The device is used for at least an average of 4 hours per 24-hour period;
C. None of the following contraindications:
   1. Baseline FIO_2 requirement > 0.40;
   2. PEEP > 10 cm H_2O;
   3. Need for continuous invasive monitoring.

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, such as COPD and sleep apnea) require **secondary review** by a medical director.

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, thoracic restrictive disease, or chronic respiratory failure following COPD.

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. For example, 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;
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;
    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.[2,11]

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.[1,11]

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.[1-3]

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.[12,13]

Coding Implications

HCPCS Codes	Description
E0466	Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)
E0465	Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube)

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 ≤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 (hypercapneic) respiratory failure or inability to maintain airflow". Replaced "tachypnea (respirations >24)" with "including tachypnea, increased work of breathing, hypoxemia, hypercapnia and/or 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 "FIO_2 requirement > 0.40". Moved invasive ventilator criteria from CP.MP.107 DME and placed in criteria IV. Combined invasive and nonivasive backup or second home ventilator into section V. Added HCPCS code E0465. Description and	06/22	06/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		

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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.

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.