Clinical Policy: Non-Invasive Home Ventilators

Reference Number: CP.MP.184 Coding Implications
Last Review Date: 05/20 Revision Log

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

Description
This policy will provide general guidelines as to when non-invasive home ventilators are or are not medically necessary.

Note: For invasive home ventilators, refer to *CP.MP.107 Durable Medical Equipment.*

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that non-invasive home ventilators are **medically necessary** for the following indications:
A. Initial request for the first three months of non-invasive 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 ≤88% for at least 5 mins while breathing prescribed O2;
b. If neuromuscular disease is present, maximal inspiratory pressure is < -60 cm H20, or forced vital capacity is < 50% predicted;
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: PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 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 (respiratory rate >24/min) and 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. FIO2 requirement > 0.40;
b. Positive-end expiratory pressure (PEEP) > 10 cm H2O;
c. Need for continuous invasive monitoring in adult patients.

B. Initial request for the first three months of non-invasive 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, 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: PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 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: include tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH <7.35);
4. None of the following contraindications:
    a. FIO2 requirement > 0.40;
    b. PEEP > 10 cm H2O;
    c. Need for continuous invasive monitoring.

C. Initial request for the first three months of non-invasive home ventilator use for obesity hypoventilation syndrome (also known as the Pickwickian Syndrome), all of the following:
1. BMI greater than 30;
2. An initial arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 45 mm Hg;
3. Respiratory failure has 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 PaCO2 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: include tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH <7.35).
    d. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsened greater than or equal to 7 mm HG compared to the original result (see C.2);
4. None of the following contraindications:
    a. FIO2 requirement > 0.40;
    b. PEEP > 10 cm H2O;
    c. Need for continuous invasive monitoring.

D. Initial request for the first three months of non-invasive 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. Criteria for respiratory failure include tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH <7.35) (PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCo2 levels alone is not considered a therapeutic failure of Bi-PAP);
   2. None of the following contraindications:
      a. FIO2 requirement > 0.40;
      b. PEEP > 10 cm H2O;
      c. Need for continuous invasive monitoring.

II. It is the policy of Health Plans affiliated with Centene Corporation that continued use of non-invasive 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. FIO2 requirement > 0.40;
   2. PEEP > 10 cm H2O;
   3. Need for continuous invasive monitoring.

III. It is the policy of Health Plans affiliated with Centene Corporation that a second or back up non-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.

IV. It is the policy of Health Plans affiliated with Centene Corporation that non-invasive home ventilators for overlap syndromes (presence of more than one condition, such as COPD and sleep apnea) require **secondary review** by a medical director.

Background

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past two decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in the critical care unit. Noninvasive ventilation has been used as a replacement for invasive ventilation, and its flexibility also allows it to be a valuable complement in patient management. Its use in acute respiratory failure is well accepted and widespread.[1]

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (e.g., volume ventilation, pressure support, bi-level positive airway pressure [BiPAP], proportional-assist ventilation [PAV], continuous positive airway pressure [CPAP]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support via an endotracheal tube or mask.[1]

Respiratory failure is not a disease, but a consequence of the problems that interfere with the ability to breathe. The term refers to the inability to perform adequately the fundamental functions of respiration: to deliver oxygen to the blood and to eliminate carbon dioxide from it. Respiratory failure has many causes and can come on abruptly (acute respiratory failure)—when the underlying cause progresses rapidly—or slowly (chronic respiratory failure)—when it is associated over months or even years with a progressive underlying process. Typically, respiratory failure initially affects the ability either to take up oxygen (referred to as oxygenation failure) or to eliminate carbon dioxide (referred to as ventilatory failure). People may live functional lives at home for many years with chronic respiratory failure. Noninvasive ventilation has also been an important advance for patients with chronic respiratory failure.[2]

Home mechanical ventilation represents a valuable therapeutic option to improve alveolar ventilation in patients with chronic respiratory failure. The primary goal of home mechanical ventilation is a reduction of symptoms, improvement of quality of life, reduce readmission risk and in many cases, reduction of mortality.[3]

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 2020, 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
E0466	Home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell)

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
E86.1	Hypovolemia
E87.70	Fluid overload unspecified
G35	Multiple sclerosis
G47.33	Obstructive sleep apnea
G47.8	Other sleep disorders
G71.09	Other specified muscular dystrophies
J96.00	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
J98.4	Other disorders of lung
J98.9	Respiratory disorder unspecified
M19.90	Unspecified osteoarthritis, unspecified site
M51.27	Other intervertebral disc displacement, lumbosacral region
N17.9	Acute kidney failure unspecified
Q99.9	Chromosomal abnormality
R06.00	Dyspnea unspecified
R53.1	Weakness
Z48.3	Aftercare following surgery for neoplasm
Z85.841	Personal history of malignant neoplasm of brain

Reviews, Revisions, and Approvals	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
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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.