

Clinical Policy: Non-Invasive Home Ventilators

Reference Number: PA.CP.MP.184

Effective Date: 5/1/2021

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Coding Implications

Revision Log

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 PA Health & Wellness® that non-invasive 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 five 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 H₂O, or forced vital capacity is < 50% predicted;
 - ii. For those < 18 years of age, documentation of Type 1 (hypoxemic) and/or Type 2 (hypercapnic) 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: 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, 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 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 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, 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, 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 FIO₂ requirement > 0.40;
 - b. PEEP > 10 cm H₂O;
 - 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 PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂, 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 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, increased work of breathing, hypoxemia, hypercapnia, and/or 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. Baseline FIO₂ requirement > 0.40;
 - b. PEEP > 10 cm H₂O;
 - 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 PaCO₂ levels alone is not considered a therapeutic failure of Bi-PAP);
 2. None of the following contraindications:
 - a. Baseline FIO₂ requirement > 0.40;
 - b. PEEP > 10 cm H₂O;
 - c. Need for continuous invasive monitoring.

- II. It is the policy of PA Health & Wellness 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 four hours per 24-hour period;
 - C. None of the following contraindications:
 1. Baseline FIO₂ requirement > 0.40;
 2. PEEP > 10 cm H₂O;
 3. Need for continuous invasive monitoring.

- III. It is the policy of PA Health & Wellness 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 PA Health & Wellness 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 PA Health & Wellness 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.^{1,2,3}

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.^{12,13}

Coding Implications

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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 non-invasive 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 $\leq 88\%$ O ₂ 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 PA.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	
New PHW policy adopted	5/20/2021	
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 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 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	7/29/2022	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
header to “Revision Date.” References reviewed and updated. Specialist reviewed.		
Annual review completed. Minor rewording with no clinical significance. Background updated with no clinical significance. References reviewed and updated.	06/2023	

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