



**Applicable To:**

- Medicaid – All Markets (excluding AZ and KY)
- Medicare – All Markets
- Children's Medical Services Health Plan (CMS Health Plan)

*Missouri Care, 'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, OneCare (Care1st Health Plan Arizona, Inc.), Staywell of Florida, Children's Medical Services Health Plan, WellCare (Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas), WellCare Prescription Insurance, WellCare Texan Plus (Medicare – Dallas & Houston markets)*

**Non-Invasive  
Home Ventilators**

**Policy Number: HS-489**

**Original Effective Date: 5/27/2019**

**Revised Date(s): N/A**

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**DISCLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

**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.<sup>1</sup>

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.<sup>1</sup>

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.<sup>2</sup>

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 and in many cases reduction of mortality.<sup>3</sup>

Documentation to support the medical necessity of a ventilator includes a valid prescription (order) that includes:

- Beneficiary's name
- Date of the order
- A general description, a HCPCS code, a HCPCS code narrative, or a brand name/ model number of all items separately billed
- Prescribing practitioner's signature, date and NPI
- For separately billed supplies: frequency of use (if applicable), and the quantity dispensed
- Payable diagnosis
- Medical necessity documented in the medical record
- Ventilator setting
- Proof of delivery
- Documentation describing the supplier's backup plan in case the primary ventilator breaks down

## POSITION STATEMENT

### Exclusions

Neonatal or pediatric home ventilators are covered under the separate state requirements and excluded from the criteria detailed in this clinical coverage guideline.

Non-Invasive home ventilators are not considered medically necessary and not a covered benefit for members when any of the following contraindications apply:

1. FIO<sub>2</sub> requirement > 0.40,
2. PEEP > 10 cm H<sub>2</sub>O
3. Need for continuous invasive monitoring in adult patients

Overlap Syndromes: Not infrequently a member will qualify for a Respiratory Assist Device for more than one condition (Overlap Syndromes) such as a combination of COPD and Sleep Apnea. This will require physician review and judgement to determine which the dominant issue is, and whether a request for a Ventilator is justified by the clinical facts in the record.

### Coverage

#### **Non-invasive home ventilators for restrictive thoracic disorders:**

Non-Invasive home ventilators are considered medically necessary and a covered benefit for members with a restrictive thoracic disorder when the member meets all of the following criteria:

1. Member has documentation of a neuromuscular disease (ex. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (ex. post-thoracoplasty for TB or Severe Kyphoscoliosis); **AND**,

2. Member has had an arterial blood gas PaCO<sub>2</sub>, done while awake and breathing and one of the following apply:
  - A. the beneficiary's prescribed FIO<sub>2</sub> is greater than or equal to 45 mm Hg, **OR**,
  - B. If member has a neuromuscular disease, Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O, **OR** forced vital capacity is less than 50% predicted,

**AND,**

3. Respiratory failure has failed to improve with an adequate trial of Bi-PAP as evidenced by one of the following: NOTE - PaCO<sub>2</sub> levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO<sub>2</sub> levels alone is not considered a therapeutic failure of Bi-PAP
  - A. Patient intolerance, as indicated by patient request to discontinue nocturnal assisted ventilation, **OR**,
  - B. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia, **OR**,
  - C. Signs of respiratory failure: include tachypnea (respiratory rate >24/min) and respiratory acidosis (eg, pH <7.35).

**AND,**

4. Chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary Limitation (spirometry shows an FEV<sub>1</sub>/FVC greater than or equal to 70%)

**Non-invasive home ventilators for Severe Chronic Obstructive Pulmonary Disease**

Non-Invasive home ventilators are considered medically necessary and a covered benefit for members with a severe COPD when the member meets all of the following criteria:

1. Member has had an arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, is greater than or equal to 52 mm Hg; **AND**,
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 there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation

**AND,**

3. Respiratory failure has failed to improve with an adequate trial of Bi-PAP as evidenced by one of the following: NOTE - PaCO<sub>2</sub> levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO<sub>2</sub> levels alone is not considered a therapeutic failure of Bi-PAP
  - D. Patient intolerance, as indicated by patient request to discontinue nocturnal assisted ventilation, **OR**,
  - E. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia, **OR**,
  - F. Signs of respiratory failure: include tachypnea (respiratory rate >24/min) and respiratory acidosis (eg, pH <7.35).

**Non-invasive home ventilators for Obesity Hypoventilation Syndrome (also known as the Pickwickian Syndrome):**

Non-Invasive home ventilators are considered medically necessary and a covered benefit for members with Obesity Hypoventilation Syndrome when the member meets all of the following criteria:

1. Member has a BMI greater than 30; **AND**,
2. Member has had an initial arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, is greater than or equal to 45 mm Hg; **AND**,
3. Spirometry shows an FEV<sub>1</sub>/FVC greater than or equal to 70%.

**AND,**

4. Respiratory failure has failed to improve with an adequate trial of Bi-PAP as evidenced by one of the following: NOTE - PaCO<sub>2</sub> levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO<sub>2</sub> levels alone is not considered a therapeutic failure of Bi-PAP
  - A. Patient intolerance, as indicated by patient request to discontinue nocturnal assisted ventilation, **OR**,
  - B. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia, **OR**,

- C. Signs of respiratory failure: include tachypnea (respiratory rate >24/min) and respiratory acidosis (eg, pH <7.35).

**AND,**

5. One of the following applies to the member:
- A. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5; **OR,**
  - B. An arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO<sub>2</sub>, shows the beneficiary's PaCO<sub>2</sub> worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).

**Non-invasive home ventilators for members who have experienced treatment failure with Bi-PAP:**

Non-Invasive home ventilators are considered medically necessary and a covered benefit for members who have failed treatment with a Bi-PAP and meet all of the following criteria:

1. Member has intolerance to Bi-PAP, as indicated by patient request to discontinue nocturnal assisted ventilation; **OR,**
2. Member has worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia; **OR,**
3. Member has signs of respiratory failure. Criteria for respiratory failure include tachypnea (respiratory rate >24/min) and respiratory acidosis (eg, pH <7.35) (PaCO<sub>2</sub> levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO<sub>2</sub> levels alone is not considered a therapeutic failure of Bi-PAP.)

**Continued Coverage Criteria for all indications:**

Initial coverage for a non-Invasive home ventilator is for a 3 month period. Continued coverage criteria ensures that the device is beneficial and is being used appropriately. For continued coverage of a non-invasive home ventilator member must meet all of the following criteria:

1. Medical records must show documentation that the member has benefited from the device citing improvement in relevant signs or symptoms; **AND,**
2. The member is compliant with usage, by using the device for at least an average of 4 hours per 24-hour period; **AND,**
3. A repeat arterial blood gas (ABG) is documented prior to requesting continued coverage.

**CODING**

The following diagnosis codes will be denied if submitted as the only primary and/or secondary diagnoses:

**G47.33** Organic sleep apnea  
**Z93.0** Tracheostomy status

The following codes should be used only to indicate the presence (without need for care) of an artificial opening such as a tracheostomy, colostomy, or cystostomy and should only be reported as secondary diagnoses:

**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

**Diagnosis Codes Covered <sup>4</sup>**

- E0466** Home ventilator, any type, used with non-invasive 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

**Exclusion Criteria**

- The following codes are not eligible diagnoses for Medicare coverage:
  - **G47.33** Organic sleep apnea
  - **G47.3** Sleep apnea
- If both a ventilator and a PAP device (E0601, E0470, E0471) are billed, the CPAP/BiPAP device will be denied as not medically necessary.
- Ventilators fall into the “Frequently & Substantially Serviced” payment category, and neither repairs nor maintenance and servicing are covered. The monthly rental fee covers all maintenance and repair issues.

**Ventilator With Noninvasive Interfaces <sup>8</sup>**

Ventilators (E0465, E0466) are covered for the following conditions:

- Neuromuscular diseases
- Thoracic restrictive diseases
- Chronic respiratory failure consequent to chronic obstructive pulmonary disease

For additional information, [click here](#).

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member’s benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.

**REFERENCES**

1. Insert Soo Hoo, G.W. Noninvasive Ventilation. Medscape. Updated October 22, 2018. <https://emedicine.medscape.com/article/304235-overview>. Accessed May 15, 2019.
2. Breathing in America: Diseases, progress, and hope. American Thoracic Society. Published 2010. <https://www.thoracic.org/patients/patient-resources/breathing-in-america/>. Accessed May 15, 2019.
3. Huttmann, S.E., Storre, J.H., Windisch, W. Home mechanical ventilation: Invasive and noninvasive ventilation therapy for chronic respiratory failure. Anaesthetist. 64(6):479-86. Published June 2015. Accessed at <https://www.ncbi.nlm.nih.gov/pubmed/26065554>. Accessed on May 15, 2019.
4. Local Coverage Determination: Respiratory Assist Devices (L33800). Published October 9, 2015 (revised January 1, 2017). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Accessed May 15, 2019.
5. Simonds, A.K. Home mechanical ventilation: An overview. Annals of the American Thoracic Society. Vol. 13, No. 11. Published November 1, 2016. Accessed at <https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201606-454FR>. Accessed on May 15, 2019.
6. AARCH Clinical practice guideline – Long-term invasive mechanical ventilation in the home. American Association for Respiratory Care. Revised 2007. <http://rc.rcjournal.com/content/respcare/52/8/1056.full.pdf>. Accessed May 15, 2019.
7. Gay, P.C. Nocturnal ventilator support in COPD. UpToDate. Updated April 29, 2019. [www.uptodate.com](http://www.uptodate.com). Accessed May 15, 2019.
8. National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03, Chapter 1, Part 4, Section 280.1). Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html>. Accessed May 15, 2019.

**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

Date	Action
5/27/2019	• Approved by MPC. New.