MEDICAL POLICY STATEMENT
Arkansas PASSE

Policy Name & Number	Date Effective
Noninvasive Home Mechanical Ventilation-AR PASSE-MM-1702	12/01/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Noninvasive Home Mechanical Ventilation

B. Background

This document outlines the medical necessity criteria for a noninvasive home ventilator for a member with stable, chronic respiratory failure. This device does not treat the underlying cause of respiratory failure but functions as supportive therapy, which may include reducing symptoms, improving quality of life, or sustaining or extending life. It may be used intermittently during the day and/or during sleep.

A noninvasive home ventilator will not be reimbursed as such when its sole purpose is to function as a respiratory assistance device, including continuous positive airway pressure (CPAP), auto-titrating PAP, and bilevel airway pressure (BiPAP).

C. Definitions

- **Apnea-Hypopnea Index (AHI)** – The combined average number of apneas and hypopneas that occur per hour of sleep to determine the severity of obstructive sleep apnea (OSA).

Apnea-Hypopnea Index (AHI)		
	Adult AHI	**Pediatric AHI**
Mild OSA	5 -14	1 - 4.9
Moderate OSA	15 - 30	5 - 9.9
Severe OSA	> 30	> 10

- **Bi-level Positive Airway Pressure (BiPAP) Device** – A device that uses mild bi-level or 2 levels of air pressure to keep breathing airways open.
- **Continuous Positive Airway Pressure (CPAP) Device** – A device that uses mild continuous air pressure to keep breathing airways open.
- **Home Mechanical Ventilation (HMV)** – A device used in the home setting for patients with chronic respiratory failure that delivers respiratory assistance via an invasive (ie, tracheostomy) or noninvasive (ie, nose/mouth mask, mouthpiece, nasal prongs) interface. These devices possess more advanced features than a CPAP/BiPAP machine, which include monitoring, rate control, safety, and backup power features. The ventilator can custom control all phases of the breathing cycle.

D. Policy

I. CareSource utilizes Arkansas Department of Human Services and MCG Health criteria to determine medical necessity for noninvasive HMV (E0466). An initial approval for HMV is valid for a maximum of 3 months. A new medical necessity determination thereafter is required every 6 months for continued rental use.

II. Initial Rental of HMV

Medical necessity for the initial coverage of noninvasive HMV is based upon the following conditions in II - IV being met:

A. Congenital central hypoventilation syndrome

B. Chronic lung disease of infancy (eg, bronchopulmonary dysplasia), and patient unable to maintain acceptable pH and PCO_2 without ventilator support
C. Chronic obstructive pulmonary disease (COPD) and **ONE OR MORE** of the following:
    1. Chronic hypercapnia with $PaCO_2$ of 50 mm Hg (6.7 kPa) to less than 52 mm Hg (6.9 kPa) and at least **ONE** of the following:
        a. Arterial oxygen saturation ≤ 88% for 5 consecutive minutes during nocturnal oximetry while on at least 2 liters of oxygen per minute.
        b. Invasive or noninvasive ventilation for acute exacerbation required during 2 or more hospitalizations per year.
    2. Chronic hypercapnia with $PaCO_2$ of 52 mm Hg (6.9 kPa) or greater.
    3. Palliative care for end-stage disease and advance directive states no desire for intubation.
D. Neuromuscular disorder accompanied by chronic respiratory failure, as indicated by the following:
    Documentation of respiratory failure, as indicated by **ONE OR MORE**:
    1. Arterial O_2 saturation less than 88% for 5 consecutive minutes during nocturnal oximetry
    2. Daytime PCO_2 (arterial or capillary) greater than 45 mm Hg (6.0 kPa)
    3. Forced vital capacity less than 50% of predicted
    4. Forced vital capacity less than 80% of predicted and symptoms of respiratory failure
    5. Maximum inspiratory pressure 60 cm H_2O (5884 Pa) or lower
    6. Maximum sniff nasal inspiratory pressure less than 40 cm H_2O (3923 Pa)
    7. Polysomnography demonstrates sleep hypoventilation, as indicated by **ONE OR MORE** of the following:
        a. Adult with sleep-related hypoventilation (ie, arterial, end-tidal, or transcutaneous PCO_2 greater than 55 mm Hg (7.3 kPa) for 10 minutes or longer, or increase in arterial, end-tidal, or transcutaneous PCO_2 of 10 mm Hg (1.3 kPa) or greater above awake supine value resulting in PCO_2 greater than 50 mm Hg (6.7 kPa) for 10 minutes or longer).
        b. Child with sleep-related hypoventilation (ie, sleeping arterial, end-tidal, or transcutaneous PCO_2 of greater than 50 mm Hg (6.7 kPa) for greater than 25% of total sleep time, or peak sleep end-tidal PCO_2 of 55 mm Hg (7.3 kPa) or greater).
E. Obesity hypoventilation syndrome, as indicated by **ALL** of the following:
    1. BMI > 30
    2. CPAP unsuccessful or not appropriate, as indicated by **ONE OR MORE** of the following:
        a. Comorbid sleep-related hypoventilation (ie, arterial, end-tidal, or transcutaneous PCO_2 greater than 55mm Hg (7.3 kPa) for 10 minutes or longer, or increase in arterial, end-tidal, or transcutaneous PCO_2 of 10 mm Hg (1.3 kPa) or greater above awake supine value resulting in PCO_2 greater than 50 mm Hg (6.7 kPa) for 10 minutes or longer)

b. Intolerance of CPAP pressures necessary to correct obstructive sleep apnea (OSA) component (ie, difficulty exhaling against fixed airway pressure)
c. Lack of resolution of hypercarbia, nocturnal desaturation, and OSA despite 3 months of CPAP use
d. Titration study demonstrates OSA despite CPAP 15 cm H_2O (1471 Pa) that is responsive to BiPAP

3. Daytime hypercapnia with $PaCO_2$ greater than 45 mm Hg (6.0 kPa) without other etiology (eg, kyphoscoliosis, lung parenchymal disease, myopathy, severe hypothyroidism)
4. Sleep-disordered breathing or hypoventilation on polysomnography, as indicated by **ONE OR MORE** of the following:
   a. Apnea-hypopnea index of 5 or greater
   b. Increase in $PaCO_2$ during sleep by more than 10 mm Hg (1.3 kPa) above value while awake
   c. Significant oxygen desaturation (eg, less than 90%) not explained by obstructive apneas or hypopneas
5. TSH level does not demonstrate hypothyroidism

F. OSA in child or adolescent and **ONE OR MORE** of the following:
1. Mild OSA (ie, apnea-hypopnea index from 1 to 5) and **ONE OR MORE** of the following:
   a. achondroplasia
   b. behavioral problems
   c. cardiovascular disease (eg, elevated blood pressure, pulmonary hypertension)
   d. Chiari malformation
   e. craniofacial abnormalities
   f. Down Syndrome
   g. excessive daytime sleepiness
   h. impaired cognition
   i. inattention or hyperactivity
   j. mucopolysaccharidoses
   k. neuromuscular disorders
   l. Prader-Willi syndrome
2. Moderate or severe OSA (ie, apnea-hypopnea index greater than 5)
3. Residual apnea-hypopnea index greater than 5 in pediatric patient after adenotonsillectomy

G. Restrictive disorder of chest wall, as indicated by **ALL** of the following:
1. Appropriate chest wall disorder as indicated by **ONE OR MORE** of the following:
   a. asphyxiating thoracic dystrophy
   b. kyphoscoliosis
   c. other chest wall disorder accompanied by chronic respiratory failure (eg, ankylosing spondylitis, fibrothorax, post-tuberculous chest wall deformity)
2. Documentation of respiratory failure as indicated by **ONE OR MORE** of the following:

a. Arterial O_2 saturation less than 88% for 5 consecutive minutes during nocturnal oximetry
b. Daytime PCO_2 (arterial or capillary) greater than 45 mm Hg (6.0 kPa)
c. Forced vital capacity less than 50% of predicted
d. Forced vital capacity less than 80% of predicted and symptoms of respiratory failure
e. Maximum inspiratory pressure 60 cm H_2O (5884 Pa) or lower
f. Polysomnography demonstrates sleep hypoventilation, as indicated by **ONE OR MORE** of the following:
   01. Adult with sleep-related hypoventilation (ie, arterial, end-tidal, or transcutaneous PCO_2 greater than 55 mm Hg (7.3 kPa) for 10 minutes or longer, or increase in arterial, end-tidal, or transcutaneous PCO_2 of 10 mm Hg (1.3 kPa) or greater above awake supine value resulting in PCO_2 greater than 50 mm Hg (6.7 kPa) for 10 minutes or longer).
   02. Child with sleep-related hypoventilation (ie, sleeping arterial, end-tidal, or transcutaneous PCO_2 of greater than 50 mm Hg (6.7 kPa) for greater than 25% of total sleep time, or peak sleep end-tidal PCO_2 of 55 mm Hg (7.3 kPa) or greater).

III. Respiratory status is STABLE, as indicated by **ALL** of the following:
   A. Airway interface is safe with a noninvasive interface with acceptable fit.
   B. Airway pressure requirement appropriate, as indicated by **ONE OR MORE** of the following:
      1. BiPAP expiratory positive airway pressure requirement is ≤ to 10 cm H_2O (981 Pa).
      2. CPAP pressure requirement in child is ≤ 15 cm H_2O (1471 Pa).
      3. Ventilator positive end-expiratory pressure requirement is ≤ 10 cm H_2O (981 Pa).
   C. Oxygen requirement does not exceed FiO_2 of 40%.
   D. Settings are stable on chosen device.
   E. No continuous invasive monitoring is required.

IV. A BiPAP or CPAP device must not be clinically appropriate as indicated by **ONE OR MORE** of the following.
   A. Chronic respiratory insufficiency fails to improve with simple BiPAP device.
   B. Infant or child does not meet the minimum body weight requirement for CPAP device.
   C. Infant or child is not appropriate for simple BiPAP device due to setting or performance requirements, as indicated by **ONE OR MORE** of the following:
      1. Breath rates delivered by device not appropriate for patient.
      2. Compatible ventilator circuits not appropriate for patient (eg, circuit compliance, compressed volume, dead space).
      3. Inspiratory flows delivered by device not appropriate for patient.
      4. Patient does not meet ventilator minimum body weight requirements.

5. Pressure range (eg, expiratory pressure, inspiratory pressure) not appropriate for patient.
6. Tidal volume range delivered by device not appropriate for patient.
7. Ventilator inspiratory trigger delay (ie, airway pressure rise time) not appropriate for patient.
8. Ventilator inspiratory trigger sensitivity not appropriate for patient.

D. The following setting or functionality is required by the member and is not available with simple BiPAP device:
1. Alarms required by member are not available on the device.
2. Daytime ventilation using mouthpiece is required.
3. Pressure range delivered by device is not appropriate for member.
4. Member requires volume-assured pressure support or volume control mode (eg, obesity hypoventilation syndrome).

E. Ventilated patient requires cough assistance via volume ventilator's breath stacking capability.

F. Ventilation is required 24 hours per day.

V. HMV Continued Use

A. For HMV continued use beyond the initial 3-month determination, medical necessity must be reestablished every 6 months thereafter. The following is to be provided for continued use:
1. Re-evaluation by the treating medical professional must be completed no earlier than 61 days after initiating therapy.
2. Documentation of the persistence of the disease process for which HMV has been prescribed.
3. Medical records must document that the member is compliant with and benefitting from HMV.
4. At least 30 consecutive days of device data, beginning after 31 days of initiation, demonstrating that the member is utilizing the device an average of 6 hours per 24-hour period. **NOTE:** Failure of the member to consistently use HMV for an average of 6 hours per 24-hour period would demonstrate non-compliant utilization of the device for its intended purpose and expectation of benefit, which would constitute a denial in continued coverage as *not reasonable and necessary*.
5. Renewals require continued care by physician with the last physical examination occurring within 1 year by the pulmonologist. Documentation of the pulmonary examination is required within 12 months of the beginning date of renewal.
6. The plan for weaning the pediatric patient with potentially reversible disease from ventilator support must be addressed and evaluated by the pulmonologist on a regular basis, at least annually.
7. Additional information as requested.

B. Within 30 working days before the end of an authorized medical necessity determination for HMV, the Provider must obtain a new prescription and submit a new completed DMS-679 form signed by the prescribing Provider.

VI. In accordance with Arkansas Department of Human Services, for each claim the provider cannot legitimately receive payment until necessary supporting documents have been obtained and placed in the provider's files. These documents include the prescription and the following items:
   A. A completed DMS form: DMS-679. The form must specify the brand name/model on the prior authorization request.
   B. Practitioner order and chart notes, which support the determination of medical necessity, including that the Member is medically dependent on a ventilator for life support at least 6 hours per day.
   C. Has been medically dependent for at least 20 consecutive days as an inpatient.
   D. Receives services under the direction of a pulmonary physician who is familiar with the technical and medical components of home ventilator support and has medically determined that in-home care is safe and feasible for the Member.

   NOTE: Per Arkansas Department of Human Services, E0466: 1 day = 1 unit.

VII. Regardless of its authorized length, a rental period ends when the rented item is no longer medically necessary.

VIII. Exclusions

Any application for a noninvasive home ventilator (E0466) not meeting the criteria above will be denied as being not medically necessary, including but not limited to when its sole purpose is to function as a respiratory assistance device, including CPAP, auto-titrating PAP, and BiPAP.

E. Conditions of Coverage

Claims for ventilators being utilized to provide CPAP or BiPAP therapy for conditions described above and are submitted with HCPCS code E0466, will be denied as not being reasonable and necessary. If a HMV is dispensed to a Member for CPAP or BiPAP therapy, the claim must be coded in accordance with CareSource policy, *Positive Airway Pressure Devices for Pulmonary Disorders Continued Rental*. All requirements in D. I.-V. of this policy must be satisfied for HMV to be considered medically necessary.

F. Related Policies/Rules

Arkansas Dept of Human Services: *Ventilator Equipment*
CareSource: Positive Airway Pressure Devices for Pulmonary Disorders Continued Rental

G. Review/Revision History

	DATE	ACTION
Date Issued	09/11/2024	Approved at Committee.
Date Revised		
Date Effective	12/01/2024	
Date Archived		

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

Independent medical review 05/08/24