MEDICAL POLICY STATEMENT
TrueCare

Policy Name & Number	Date Effective
Non-Invasive Home Mechanical Ventilation (E0466)-TrueCare-MM-1721	11/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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A. Subject

Non-Invasive Home Mechanical Ventilation

B. Background

This document outlines the medical necessity criteria for a non-invasive 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 non-invasive 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). Medical necessity for BIPAP and CPAP devices are determined based upon MCG criteria, A-0431 and A-0994.

C. Definitions

- **Apnea-Hypopnea Index (AHI)** – The combined average number of apneas and hypopneas recorded over a period of at least 2 hours without the use of a respiratory device, reported by polysomnogram. Extrapolation or projection of the AHI is not permitted.

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

- **Home Mechanical Ventilation (HMV)** – An overarching term used in this policy to describe home-based ventilatory support devices used in the management of chronic respiratory failure, encompassing a continuum of non-invasive respiratory support modalities, including respiratory assist devices (eg, CPAP, Bilevel, and volume-targeted pressure support modes such as AVAPS) and, when medically necessary, non-invasive home ventilator devices (eg, E0466). For purposes of this policy, classification within the HMV continuum is determined by clinical dependence, functional capability of the device, and medical necessity, rather than by device naming conventions alone. This policy does not address invasive mechanical ventilation delivered via tracheostomy.
- **Non-Invasive Ventilation (NIV) / Non-Invasive Home Ventilator** – Ventilatory support delivered through a non-invasive interface (eg, nasal or oronasal mask or mouthpiece) using positive airway pressure technology and includes both respiratory assist device (RADS) modes that augment spontaneous breathing and non-invasive mechanical ventilation that delivers mandatory, machine-generated breaths.
- **Respiratory Assist Devices (RADs)** – Non-invasive positive airway pressure devices, including standard BIPAP, and volume-targeted pressure support modes such as AVAPs or iVAPs, that augment spontaneous breathing but do not provide mandatory, machine-generated breaths as the primary source of ventilation and

therefore do not constitute ventilator dependency as defined within this policy. RADs are billed under E0601, E0470, E0471, and E0472.

- **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.
- **Auto EPAP (AE)** – An automated feature that adjusts expiratory positive airway pressure (EPAP) in response to airflow limitation/upper airway obstruction during non-invasive therapy.
- **Average Volume Assured Pressure Supports (AVAPS), with or without Auto-EPAP (AE)** – A volume-targeted mode of non-invasive positive airway pressure ventilation that delivers variable pressure support within prescribed limits to achieve a target ventilation (typically via a target tidal volume) and functions as a respiratory assist device that augments spontaneous breathing, rather than as a life-sustaining ventilator.
- **Intelligent Volume Assured Pressure Support (iVAPS)** – A mode of non-invasive ventilation that adjusts positive airway pressure support over time to achieve a target ventilation goal while relying on the patient's spontaneous breathing effort, similar in function to AVAPS.

- **Ventilator-Dependent (Non-Invasive)** – Describes a member who requires a device to provide mandatory, mechanical ventilation that serves as the primary, life-sustaining source of ventilation for 6 or more hours within a 24-hour period and who cannot safely maintain adequate ventilation without such mechanical assistance. Discontinuation of ventilatory support would place the member at risk of serious harm or death. Use of CPAP, standard bilevel positive airway pressure devices, or volume targeted pressure support modes (eg, AVAPS or iVAPS), when used to treat sleep apnea or mild to moderate respiratory insufficiency and to augment spontaneous breathing, does not constitute ventilator dependence and such devices are not considered non-invasive home ventilators under this policy.

D. Policy

The criteria below are intended to guide escalation from CPAP or BIPAP to a non-invasive home ventilator (E0466) only when the member's chronic respiratory failure and clinical dependence require ventilator-level support beyond the capabilities of RADs. TrueCare utilizes Mississippi Division of Medicaid (MS MCD) and MCG Health criteria to determine medical necessity for non-invasive home ventilator devices (ie, HVD; E0466). Requests that do not meet the criteria for HVD will be reviewed against MCG Health criteria for BIPAP and CPAP devices (ie, A-0431 and A-0994).

I. An initial approval for HMV is valid for a maximum of 3 months. A new medical necessity determination thereafter is required every 6 months with supporting documentation for continued rental use.

II. Medical Necessity Criteria for Initial Rental of Home Ventilatory Device
Medical necessity for the initial coverage of noninvasive HMV is based upon the following conditions in II - IV being met.
A member must have **1** of the qualifying diagnoses:
A. Congenital central hypoventilation syndrome

B. Chronic lung disease of infancy (eg, bronchopulmonary dysplasia) and member unable to maintain acceptable pH and PCO_2 without ventilator support
C. Chronic obstructive pulmonary disease (COPD) and **1 OR MORE** of the following:
    1. chronic hypercapnia (ie, $PaCO_2$ > 45 mm Hg (6.0 kPa)) in stable patient
    2. noninvasive ventilation during hospitalization with persistent hypercapnia during spontaneous breathing (ie, $PaCO_2$ > 45 mm Hg (6.0 kPa))
    3. palliative care for end-stage disease and advance directive states no desire for intubation
D. Neuromuscular disorder accompanied by respiratory failure, as indicated by **ALL** the following:
    1. Appropriate neuromuscular disorder, as indicated by **1 OR MORE** of the following:
        a. amyotrophic lateral sclerosis
        b. congential muscular dystrophy
        c. Duchenne muscular dystrophy
        d. mitochondrial myopathy
        e. myotonic dystrophy
        f. postpolio syndrome
        g. spinal cord syndrome
        h. spinal muscular atrophy
        i. other neuromuscular disorder accompanied by chronic respiratory failure (eg, multiple sclerosis, myasthenia gravis, Pompe disease)
    2. Documentation of respiratory failure, as indicated by **ONE OR MORE**:
        a. daytime PCO_2 (arterial or capillary) > 45 mm Hg (6.0 kPa)
        b. Forced vital capacity < 50% of predicted
        c. Forced vital capacity < 80% of predicted and symptoms of respiratory failure
        d. Maximum inspiratory pressure 60 cm H_2O (5884 Pa) or lower
        e. Maximum sniff nasal inspiratory pressure < 40 cm H_2O (3923 Pa)
        f. Oxygen saturation < 88% for 5 consecutive minutes during nocturnal oximetry
        g. Polysomnography demonstrates sleep hypoventilation, as indicated by **ONE OR MORE** of the following:
            i. Adult with sleep-related hypoventilation (ie, arterial, end-tidal, or transcutaneous PCO_2 > 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 > 50 mm Hg (6.7 kPa) for 10 minutes or longer).
            ii. Child with sleep-related hypoventilation (ie, sleeping arterial, end-tidal, or transcutaneous PCO_2 of > 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 > 10 mm Hg (1.3 kPa) above value while awake
   c. Significant oxygen desaturation (eg, < 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 1-5) and **ONE OR MORE** of the following when BiPAP/CPAP has been unsuccessful or not appropriate:
      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 > 5)
   3. Residual apnea-hypopnea index > 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 disorders 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 < 88% for 5 consecutive minutes during nocturnal oximetry
   b. Daytime PCO_2 (arterial or capillary) > 45 mm Hg (6.0 kPa)
   c. Forced vital capacity < 50% of predicted
   d. Forced vital capacity < 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 > 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 > 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. Settings are stable on chosen device.
   D. No continuous invasive monitoring or professional supervision is required.
   E. Trained caregivers are available.

IV. The criteria below define when a member's clinical needs exceed the capabilities of CPAP or standard BIPAP, such that consideration of a non-invasive HVD (E0466) is appropriate. 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. Portable ventilator is required for mobility.

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

G. Ventilation is required 24 hours per day.

V. Medical Necessity for Continued Device Use

For HVD 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:

A. Re-evaluation by the treating medical professional must be completed no earlier than 61 days after initiating therapy.

B. Documentation of the persistence of the disease process for which HVD has been prescribed.

C. Medical records must document that the member is compliant with and benefitting from HVD.

D. 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 HVD 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*.

E. Additional information as requested.

VI. In accordance with MS MCD Administrative Code 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 following items:

A. A face-to-face encounter related to the primary reason for requiring HMV that occurred no more than 6 months prior to the start of services with the time and date of the encounter.
B. A detailed written order including the type of equipment ordered, the length of need, and the qualifying diagnosis from D. II.
C. Practitioner order and chart notes, which support the determination of medical necessity, including ventilator settings.

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

VIII. Exclusions
A. Any request for a non-invasive home ventilator (E0466) that does not meet the medical-necessity criteria outlined above will be denied as being not medically necessary. This includes requests where the device is used solely as a respiratory assist device to augment spontaneous breathing or to treat sleep-disordered breathing, rather than to provide life-sustaining, non-invasive mechanical ventilation beyond the capabilities of respiratory assist devices such that withdrawal would place the member at risk of serious harm or death. Devices and modes that function as RAD—including CPAP, auto-titrating PAP, standard bilevel positive airway pressure (BIPAP), and volume-targeted pressure support modes such as AVAPS (with or without auto EPAP (AE), or iVAPS—do not qualify for coverage under E0466 when used for sleep apnea or mild to moderate respiratory insufficiency and do not, by themselves, establish ventilator dependency under this policy.
B. The HMV rental (E0466) includes all associated supplies that are required for appropriate use of the device and are not separately reimbursed. Servicing, repairs, and labor, including respiratory therapy visits, are included in the monthly rental fee and may not be submitted for separate reimbursement.

E. Conditions of Coverage

I. 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 HVD is dispensed to a Member for CPAP or BiPAP therapy, the claim must be coded in accordance with TrueCare policy, *Positive Airway Pressure Devices for Pulmonary Disorders Continued Rental*. All requirements in D. I.-V. of this policy must be satisfied for HVD to be considered medically necessary.

II. TrueCare may verify the use of equipment through post-payment review and request additional supporting medical record documentation. If the use of a more appropriate code or piece of equipment is warranted, TrueCare may request recoupment. Standard DME documentation requirements can be located within section D.II.A. of the administrative policy, *Medical Record Documentation Standards for Practitioners*.

F. Related Policies/Rules

Overpayment Recovery

Positive Airway Pressure Devices for Pulmonary Disorders Continued Rental Ventilator, 23-209 MISS. CODE R. § 1.44 (2024)
Medical Record Documentation Standards for Practitioners

G. Review/Revision History

	DATE	ACTION
Date Issued	03/26/2025	Approved at Committee
Date Revised	07/30/2025 07/29/2026	Revision-D.VIII. Exclusions updated; E.II added. Approved at Committee. Revised definitions; D.III.- Removed 02 cannot exceed 40%, added trained caregiver requirement; D.V. – Avg device usage 6 hours; Added documentation requirements to E.II. Approved at Committee.
Date Effective	11/01/2026	
Date Archived		

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