MEDICAL POLICY

Medical Policy Title	**Home Non-Invasive Positive Pressure Ventilation (NIPPV) Devices for Respiratory Insufficiency and Failure**
Policy Number	**1.01.57**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Neuromuscular and Thoracic Disorders

I. Bilevel positive airway pressure (BPAP) device with (HCPCS: E0471) or without (HCPCS: E0470) a backup rate is considered **medically necessary** when an individual has a neuromuscular or thoracic restrictive disease diagnosis and meets **ANY** of the following criteria:

   A. Documented decrease in forced vital capacity (FVC) to less than 80% of predicted and symptomatic (e.g. dyspnea, orthopnea or fragmented sleep) **or** less than 50% of predicted without symptoms;

   B. Maximal inspiratory pressure (MIP) of <60 cm H_2O;

   C. Oxygen desaturations ≤88% for at least five (5) cumulative minutes during sleep oximetry (minimum recording time of two (2) hours) while either breathing room air or prescribed FIO_2 as applicable; **or**

   D. Arterial blood gas (ABG) showing a $PaCO_2$ ≥45 mm Hg done while awake and breathing either room air or prescribed FIO_2 as applicable.

II. Non-invasive home mechanical ventilation (HCPCS: E0466) is considered **medically appropriate** when an individual has a neuromuscular or thoracic restrictive disease diagnosis and meets **ALL** of the following criteria:

   A. Meets criteria for a BPAP device (See Policy Statement I); **and**

   B. **One** of the following indications:

      1. Advanced BPAP with iVAPS (Intelligent Volume Assured Pressure Support) (HCPCS: E0471) does not meet the individual's respiratory needs due to **any** of the following:

         a. Need auto-expiratory positive airway pressure (EPAP);

         b. Concomitant obstructive sleep apnea (OSA);

         c. Bulbar dysfunction; **or**

         d. Concomitant chronic obstructive pulmonary disease (COPD);

2. Daytime dyspnea at rest;
3. Non-invasive ventilation is needed for greater than 10 hours per day;
4. Extreme loss in function with vital capacity less than 30%;
5. Worsening daytime hypercapnia with need for mouthpiece ventilation; **or**
6. Daytime use (battery operated unit) is required to reduce hypercapnia or dyspnea.

III. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** when **ALL** of the following are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

Hypoventilation Syndrome

IV. BPAP without (HCPCS: E0470) a backup rate is considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. An initial ABG PaCO2 greater than or equal to 45 mm Hg done while awake and breathing the patient's prescribed FIO2;

B. Spirometry shows a forced expired volume in one (1) second (FEV1)/ FVC greater than or equal to 70%; **and**

C. **One** of the following:

1. An ABG PaCO2, done when the patient is asleep or has just woken up and is breathing their prescribed FIO2, shows that PaCO2 has worsened greater than or equal to 10 mm Hg compared to the original ABG; **or**
2. A facility-based Polysomnography (PSG) or home sleep test (HST) shows oxygen saturation less than or equal to 88% for greater than or equal to five (5) cumulative minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

V. BPAP with (HCPCS: E0471) a backup rate is considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. The individual is currently using a BPAP without backup;

B. Spirometry shows an FEV1/FVC greater than or equal to 70%; **and**

C. An ABG PaCO2, done while the patient is awake and breathing their prescribed FIO2, shows the patient's PaCO2 worsens to greater than or equal to 10 mm Hg compared to the ABG result done to qualify the patient for the E0470 device.

VI. Non-invasive home mechanical ventilations devices (HCPCS: E0466) are considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. Meets criteria for BPAP (see Policy Statement IV); **and**

B. **One** of the following indications:

1. Advanced BPAP with iVAPS (Intelligent volume assured pressure support) (HCPCS: E0471) does not meet the needs of the individuals and requires auto-EPAP;
2. Non-invasive ventilation is needed for greater than 10 hours per day;
3. Severe hypoxemia with an FIO_2 greater than 40% or greater than 5L/min; **or**
4. BPAP was tried and failed (documentation of attempted daily use) with persistent hypercapnia with either of the following:
   a. Awake $PaCO_2$ ≥45 mmHg; **or**
   b. Awake venous blood gas PCO_2, end-tidal PCO_2, or transcutaneous PCO_2 ≥50 mmHg.

VII. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** for an individual when **BOTH** of the following are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

<u>Chronic Respiratory Failure (CRF) Due to Chronic Obstructive Pulmonary Disease (COPD)</u>

VIII. BPAP without (HCPCS: E0470) backup rate is considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. The individual cannot tolerate high intensity NIV or back up rate is not needed;

B. The individual exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by ABG during awake hours while breathing his/her prescribed FiO2; **and**

C. Sleep apnea has been ruled out as the cause of hypercapnia.

IX. BPAP with (HCPCS: E0471) a backup rate is considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. Meets criteria for BPAP without a backup rate (E0470) (see Policy Statement VIII);

B. Oxygen saturations ≤ 88% for at least five (5) cumulative minutes during sleep oximetry (minimum recording time of two (2) hours) while receiving oxygen at 2 LPM or prescribed FIO2, whichever is higher; **and**

C. An ABG PaCO2, done while the individual is awake and breathing their prescribed FIO2,

shows that the patient's PaCO2 worsens to greater than or equal to 10 mm Hg compared to the ABG result done to qualify the patient for the E0470 device.

X. Non-invasive home mechanical ventilation devices (HCPCS: E0466) are considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. Meets criteria for BPAP without a backup rate (E0470) (see Policy Statement VIII); **and**

B. **One** of the following:

1. Requires oxygen therapy at an FiO2 ≥36% or ≥4L nasally;
2. Requires ventilatory support for more than 8 hours per 24-hour period;
3. Requires the alarms and internal battery, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted; **or**
4. Advanced BPAP with iVAPS (Intelligent volume assured pressure support) (HCPCS: E0471) does not meet the needs of the individuals and requires auto-EPAP based that the individual is unable to meet **one** of the following:
   a. Normalization (<46 mm Hg) of PaCO2;
   b. Stabilization of a rising PaCO2;
   c. 20% reduction in PaCO2 from baseline value; **or**
   d. Improvement of at least one symptom associated with chronic hypercapnia (e.g., headache, fatigue, shortness of breath, confusion, or sleep quality).

XI. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-Invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** when **BOTH** of the following criteria are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

<u>Obstructive Sleep Apnea (OSA)</u>

XII. BPAP with (HCPCS: E0471) or without (HCPCS: E0470) back up rate is considered **medically appropriate** for an individual with OSA who meets **ALL** of the following indications:

A. Failed or cannot tolerate CPAP;

B. Demonstration of resolution or control of respiratory events with improved tolerance using BPAP at least two (2) weeks after an acute episode; **and**

C. The individual is stable on current treatment.

Sleep Apnea - Other

XIII. BPAP with (HCPCS: E0471) or without (HCPCS: E0470) a backup rate is considered **medically appropriate** for an individual with central sleep apnea (primary or secondary to medication or substance use, heart failure or medical condition), complex sleep apnea and treatment emergent sleep apnea who meet **ONE** of the following indications:

A. Central hypopnea/apnea >50% of the total apnea hypopnea index rate;

B. Central hypopnea/apnea rate/index >5 (five) events per hour;

C. Documentation supporting the effectiveness of BPAP therapy during PSG; **or**

D. Symptomatic patients with excessive sleepiness, disrupted sleep or significant desaturations despite optimized CPAP therapy.

Hospital Discharge

XIV. Hospital discharge with a home mechanical ventilator (HCPCS: E0466) or a BPAP with backup (HCPCS: E0471) rate for individuals with acute on chronic respiratory failure due to COPD and meet **BOTH** of the following indications:

A. The individual required a ventilator or a BPAP device within 24 hours prior to discharge; **and**

B. The individual is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

Continuation of Use

XV. Continuation of use of an non-invasive home mechanical ventilation device for the diagnosis of COPD, OSA and hypoventilation syndrome are considered **medically appropriate** when compliance is demonstrated by using the device for 70% of the nights for four (4) or more hours per 24-hour period during a consecutive 30-day period.

Durable Medical Equipment (DME) Repair

XVI. Repair of a medically necessary home non-invasive positive pressure ventilation (NIPPV) devices or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** the following:

1. Date of DME initiation;
2. Manufacturer warranty information, if applicable;
3. Attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of the DME;

B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. Inadequate function interferes with activities of daily living; and
2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

XVII. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

XVIII. Replacement of a medically necessary home non-invasive positive pressure ventilation (NIPPV) devices or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

XIX. The replacement of a properly functioning home non-invasive positive pressure ventilation (NIPPV) devices, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

XX. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

XXI. Accessories or components for home non-invasive positive pressure ventilation (NIPPV) devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment (DME) and Devices, Standard and Non-Standard

1.01.06 Continuous Positive Airway Pressure (CPAP) and Auto-Adjusting Positive Airway Pressure (APAP)

1.01.07 Medical Management for Obstructive Sleep Apnea (OSA)

1.01.15 Airway Clearance Devices

2.01.28 Sleep Studies

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Individuals who do not meet the criteria for continuation of coverage during the initial 90 day

trial are eligible to re-qualify for a home ventilation devices, but must have a clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to ventilation therapy (e.g., documentation of failure of symptoms to resolve or improper fit of device, and re-education of the individuals regarding proper use of the equipment or re-fitting of masks).

II. BPAP with expiratory relief are options for patients who cannot tolerate the high constant air pressure associated with CPAP but wish to continue treatment for OSA.

III. BPAP devices may or may not include a backup rate. BPAP devices with a backup rate are timed devices that supply breaths at a specific rate per minute. These devices will deliver a breath when the minimum number of breaths per minute has not been met by the user.

IV. Supplemental oxygen or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.

V. Coverage is allowed for a one-month rental when the home ventilation device is malfunctioning and out of warranty, (and not associated with a manufacturer recall) while the device is being repaired.

VI. The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components, and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.

VII. Devices used to clean or sanitize BPAP devices are considered a convenience item and are **ineligible for coverage** (e.g., SoClean, SoClean 2 Go).

DESCRIPTION

Bilevel Positive Airway Pressure (BPAP) (i.e. Simple BPAP)

BPAP is an airway support system, which provides two different levels of pressure delivered via a mask. There is a higher-pressure during inspiration and a lower pressure level during expiration. BPAP is an option for individuals who cannot tolerate the high constant air pressure associated with CPAP. BPAP devices with volume and/or pressure with a back-up rate feature are types of ventilators that can be used for many applications (as described below) but have not shown effectiveness for treating OSA. Bilevel positive pressure devices are used as respiratory assist devices for individuals with chronic respiratory failure in the following situations:

- At night for the management of chronic respiratory failure;
- For the long-term management of neuromuscular disorders with respiratory involvement;
- For patients with respiratory insufficiency due to severe kyphoscoliosis; or
- For the improvement of nighttime desaturation and hypoventilation in patients with chest-wall diseases.

Advanced BPAP

Advanced BPAP includes all the baseline functions of a standard BPAP but includes additional ventilation modes that automatically respond to the patient's real-time respiratory needs. The machine has adaptive volume/pressure support with backup rate. Typically, these machines are designed for:

- Complex or central sleep apnea;
- Cheyne-Stokes respiration;
- Obesity hypoventilation syndrome;
- Other irregular ventilation patterns.

Non-Invasive Positive Pressure Ventilation (NIPPV)

NIPPV involves the delivery of oxygen into the lungs via positive pressure without the need for endotracheal intubation. It is used in both acute and chronic respiratory failure but requires careful monitoring and titration to avoid complications. NIPPV is increasingly being used to treat individuals with chronic respiratory failure (e.g., neuromuscular diseases, restrictive thoracic disorders, obstructive lung diseases), and other hypoventilation conditions. NIPPV is a type of mechanical ventilation that can be used at home to assist with taking full breaths and maintaining adequate oxygen supply in the body, especially while sleeping. Intermittent positive pressure reduces the work of breathing through three different methods. By applying positive end-expiratory pressure (PEEP) through expiratory positive airway pressure (EPAP), positive pressure ventilation allows the body to overcome the dynamic intrinsic positive end expiratory pressure threshold required to initiate a breath, as well as increasing lung compliance.

Non-Invasive Dual or Multifunction Home Mechanical Ventilators (VOCSN, VOCSN VC, VOCSN VC Pro)

Non-invasive dual or multifunction home mechanical ventilators are life-support devices that combine mechanical ventilation with at least two additional respiratory functions, such as supplemental oxygen delivery, cough assistance, suction, nebulizer delivery, and oximetry in a single portable unit

Hypoventilation Syndromes

Hypoventilation syndromes are nonspecific disorders that are characterized by hypercapnia a $PaCO_2$ greater than 45 mmHg, and sometimes hypoxemia, especially during sleep with PaO_2 of less than 60 mmHg. Hypoventilation syndrome categories can be categorized as obesity hypoventilation syndrome, central sleep apnea and hypercapnic respiratory failure (not COPD).

Neuromuscular and Thoracic Restrictive Diseases

Neuromuscular disorders (muscular dystrophy, Amyotrophic Lateral Sclerosis (ALS), polio, and phrenic neuropathies) can result in weakness of the respiratory muscles, resulting in hypoventilation. Thoracic restrictive disorders can be caused by various underlying diseases that are characterized by pulmonary function testing showing patterns of restriction or respiratory muscle weakness with reductions in MIP and/or maximal expiratory pressure (MEP).

Central Apneas

Central sleep apnea is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with no respiratory effort noted. The cessation in breathing can be caused by problems involving brain mechanisms, or an obstructive component. Approximately 4% of individuals undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

Mixed Apneas

Mixed sleep apnea is a combination of obstructive and central sleep apnea. Not only does the patient have an obstruction in the airway, but the patient may have a neurological dysfunction or cardiopulmonary as well that contributes to the central apnea component.

Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder caused by upper-airway obstruction, most often from relaxed throat muscles during sleep. In adults, OSA involves recurrent episodes of complete or partial upper airway blockage lasting more than 10 seconds and is commonly linked to obesity, male sex, aging, and anatomical factors. Symptoms include loud snoring, witnessed apneas, gasping, excessive daytime sleepiness, and hypertension, and diagnosis requires polysomnography or home sleep testing with evidence of clinical impairment. Untreated adult OSA increases the risk of hypertension, heart failure, atrial fibrillation, other arrhythmias, and nonalcoholic fatty liver disease.

Pediatric OSA, typically caused by enlarged tonsils and adenoids, is defined by prolonged partial obstruction or intermittent complete obstruction lasting at least two respiratory cycles and may present with snoring, breathing pauses, restless sleep, behavioral issues, or poor growth. If left untreated, children may experience growth abnormalities, neurologic problems, or cor pulmonale. Polysomnography (PSG) is the preferred diagnostic tool, although normative AHI/RDI values for children are not well established. Adenotonsillectomy is first-line therapy for pediatric OSA, while persistent cases or those with contraindications may require CPAP, observation, medications, or additional airway surgery. Obstructive hypoventilation (OH), a related condition in children, may present with normal AHI but episodes of hypercarbia indicated by elevated end-tidal CO_2.

SUPPORTIVE LITERATURE

Sarasate et al (2023) reported the results of a randomized, multicenter clinical trial evaluating whether initiating non-invasive ventilation (NIV) earlier in patients with ALS, at a FVC threshold of 75%, improves outcomes compared with standard initiation at 50%. Forty-two patients were randomized to early or standard NIV, and survival time to death or tracheostomy was the primary outcome. Although early NIV was associated with longer median survival and lower mortality incidence, these differences did not reach statistical significance. Nevertheless, early NIV demonstrated benefits in slowing respiratory muscle decline, reducing adverse events, and showing good tolerance and adherence without impairing sleep quality. Overall, while the primary survival endpoint was not met, all findings favored early NIV, supporting earlier respiratory assessment and NIV initiation around an FVC of 75% in ALS patients.

Wang et al (2019) conducted a systematic review to assess the effectiveness of home noninvasive NIPPV (home mechanical ventilation (HMV), BPAP, or CPAP devices) in adults with chronic respiratory failure. 68 studies evaluating 53,733 patients were included. In patients with COPD, home BPAP (compared to no device) was associated with lower mortality, decreased need for intubations and hospital admissions, but no change in quality of life. In patients with COPD, HMV (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions. In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality. In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life. In patients with obesity hypoventilation syndrome, home HMV/BPAP (compared to no device) was associated with lower mortality. Current evidence was not available to assess the comparative effectiveness of many device capabilities on patient outcomes. Criteria to initiate home NIPPV and home respiratory services varied and were not validated in comparative studies.

Patil et al (2019) conducted a systematic review and meta-analysis of 184 studies to evaluate the effectiveness of PAP therapy for adults with OSA. CPAP significantly reduced AHI by 23 events/hour versus no treatment—an 86% reduction from 32.7 to 4.1 events/hour. CPAP also improved daytime sleepiness by 2.4 points in symptomatic patients and showed clinically meaningful benefits for sleep-related quality of life, blood pressure, and motor vehicle crash risk. Observational evidence suggested reductions in cardiovascular events and mortality, though RCTs did not confirm these outcomes. No major differences were found among CPAP, APAP, and BPAP for individual clinical outcomes, supporting CPAP as first-line therapy unless not tolerated. Home-based versus in-lab APAP initiation showed comparable results. Education, behavioral interventions, and telemonitoring improved adherence. Nasal masks enhanced adherence and reduced AHI more effectively than oronasal masks. Humidification reduced side effects without improving adherence or outcomes. Overall, CPAP reliably reduces OSA severity, improves sleepiness, and lowers blood pressure, particularly in symptomatic or hypertensive adults. Benefits for asymptomatic individuals and long-term cardiovascular outcomes remain uncertain.

Khamankar et al (2018) reported the results of this retrospective cohort study evaluating whether earlier initiation and optimized use of NIV improves survival in patients with ALS. Among 474 patients, those who used BPAP had significantly longer survival than non-users. With survival increasing progressively when BPAP was initiated at higher FVC thresholds (<50% (20.3 months); ≥50% (23.60 months); ≥80% (25.36 months). Longer daily BPAP use (>8 hours/day), and combined daily use of Bi-PAP with cough assist were each associated with significant survival benefits, whereas cough assist alone had minimal impact. Higher functional status at initiation correlated with better outcomes, and time since symptom onset was not a reliable indicator for starting NIV. Overall, an optimized NIV strategy—early BPAP initiation, sustained daily use, and concurrent cough assist—was associated with markedly prolonged survival compared with standard, later initiation protocols, supporting earlier access to and combined use of NIV interventions in ALS care.

PROFESSIONAL GUIDELINE(S)

The 2025 American Academy of Sleep (AASM) reported guidelines for the treatment of central sleep

apnea (CSA) in adults, stating:

- "Suggests using continuous positive airway pressure over no continuous positive airway pressure in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, low certainty of evidence)
- "Suggests using bilevel positive airway pressure with a backup rate over no bilevel positive airway pressure with a backup rate in adults with CSA due to the following etiologies: primary CSA, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, very low certainty of evidence)
- "Suggests against the use of bilevel positive airway pressure without a backup rate in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, very low certainty of evidence)
- "Suggests using adaptive servo-ventilation over no adaptive servo-ventilation in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, low certainty of evidence)

The 2023 American College of Chest Physicians Clinical Practice Guidelines and Expert Panel Report for the respiratory management of patients with neuromuscular weakness state:

- "Patients with neuromuscular disease (NMD) and chronic respiratory failure- they recommend using NIV for treatment with any of the following indications (indications can vary depending on age, NMD, and rate of the disease progression):
    - Any fall in FVC to < 80% of predicted with symptoms;
    - FVC to < 50% of predicted without symptoms;
    - Maximum inspiratory pressure (MIP) to < –60 cm H2O;
    - Maximum expiratory pressure (MEP) of < 40 cm H2O;
    - Based on the polysomnography results if polysomnography was indicated or the presence of hypercapnia (awake PaCO2 > 45 mm Hg)."

The American Thoracic Society released their 2020 guidelines for long-term noninvasive ventilation in chronic stable hypercapnic COPD defined as, FEV1/FVC less than 0.70; resting PaCO2 greater than 45 mm Hg; not during exacerbation. The guidelines state:

- "Suggests the use of nocturnal noninvasive ventilation (NIV) in addition to usual care for patients with chronic stable hypercapnic COPD." (conditional recommendation, moderate certainty).
- "Suggests that patients with chronic stable hypercapnic COPD undergo screening for obstructive sleep apnea before initiation of long-term NIV." (conditional recommendation, very low certainty).

- "Suggests not initiating long-term NIV during an admission for acute on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIV at 2–4 weeks after resolution." (conditional recommendation, low certainty).
- "Suggests not using an in-laboratory overnight PSG to titrate NIV in patients with chronic stable hypercapnic COPD who are initiating NIV." (conditional recommendation, very low certainty).
- "Suggest NIV with targeted normalization of PaCO2 in patients with hypercapnic COPD on long-term NIV." (conditional recommendation, low certainty).

The European Respiratory Society (ERS) and the American Thoracic Society (ATS) Clinical Recommendation for Non-Invasive Ventilation (NIV) in Adults with Acute Respiratory Failure (Rochwerg 2017) state:

- "Bilevel NIV for individuals with acute respiratory failure (ARF) leading to acute or acute-on-chronic respiratory acidosis (pH <7.35) due to COPD exacerbation." (Strong recommendation, high certainty of evidence.)
- "Either bilevel NIV or CPAP for individuals with ARF due to cardiogenic pulmonary oedema." (Strong recommendation, moderate certainty of evidence.
- "Early NIV for immunocompromised individuals ARF." (Conditional recommendation, moderate certainty of evidence.)
- "Due to the uncertainty of evidence ERS/ATS is unable to offer a recommendation on the use of NIV for de novo ARF."
- "NIV for individuals with post-operative ARF." (Conditional recommendation, moderate certainty of evidence.)
- "NIV to dyspneic individuals for palliation in the setting of terminal cancer or other terminal conditions." (Conditional recommendation, moderate certainty of evidence.)
- "NIV should not be used in the treatment of patients with established post-extubation respiratory failure." (Conditional recommendation, low certainty of evidence.

American Academy of Sleep Medicine (ASSM 2008) Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patient with OSA state:

- "Pre-Titration Preparation: All candidates should receive PAP education, hands-on demonstration, careful mask fitting, and acclimatization." (Standard)
- "Transition to BPAP: If a patient is uncomfortable or intolerant of high CPAP pressures, or obstructive respiratory events continue at 15 cm H2O, switch the patient to BPAP." (Consensus)
- "Repeat Titration Study: Consider repeating a titration if the initial titration was not optimal/good and, for split-night studies, fails to meet AASM criteria." (Consensus)

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates BPAP and home ventilators as

medical devices. All BPAP and home ventilators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 May 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 May 26]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A7027-A7039	Accessories/supplies, code range for positive pressure airway devices (code range)
A7044-A7046	Accessories/supplies, code range for positive pressure airway devices (code range)
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E0466	Home ventilator, any type, used with noninvasive 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 (i.e., multi-function home ventilator)

Code	Description
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions (i.e., dual-function home ventilator)
E0470	Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) (i.e., Simple BPAP)
E0471	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device

ICD10 Codes

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G12.0-G12.9	Spinal muscular atrophy and related syndromes (code range)
G35	Multiple sclerosis
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.35	Congenital central alveolar hypoventilation syndrome
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified

Code	Description
I50.9	Heart failure, unspecified
J39.8	Other specified diseases of upper respiratory tract
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J96.00-J96.02	Acute respiratory failure (code range)
J96.10-J96.12	Chronic respiratory failure (code range)
J96.20-J96.22	Acute and chronic respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia (code range)
J98.4	Other disorders of lung
J98.8	Other specified respiratory disorders

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Respiratory Assist Devices (LCD L33800) [accessed 2026 May 27]

Durable Medical Equipment Reference List (NCD 280.1) [accessed 2026 May 27]

Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD) (NCD 240.9) [accessed 2026 May 27]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date