Anthem

Clinical UM Guideline

Subject: Noninvasive Home Ventilator Therapy for Respiratory Failure
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Description

This document addresses the medically necessary indications for home use of noninvasive home ventilators. A home ventilator is a mechanical device capable of providing pressurized air with or without supplemental oxygen and two or more of the following features: pressure support; rate support; volume support; or various combinations of pressure, rate, and volume support. A noninvasive home ventilator delivers the air through a mask or nasal interface tightly sealed to the face.

Notes: This document *does not address* the use of ventilation therapy:

- Of hospitalized individuals;
- With a device that does not match this document's definition of a ventilator;
- For the treatment of obstructive sleep apnea (OSA);
- Through a tracheostomy.

Clinical Indications

Medically Necessary:

Noninvasive positive pressure ventilation therapy (NPPV) with a home ventilator is considered **medically necessary** for the following conditions (A, B, **or** C):

A. The primary cause of respiratory failure is neuromuscular disease (for example, amyotrophic lateral sclerosis) or restrictive thoracic disease (for example, thoracic cage abnormalities) when either of the following criteria 1 **or** 2 are met:
   1. An arterial blood gas $PaCO_2$ level is greater than or equal to 45 mm Hg while awake and breathing the individual's usual FIO_2; **or**
   2. The individual has a maximum inspiratory pressure of less than or equal to 60 cm H_2O.

   or
B. Hypercapnic end-stage chronic obstructive pulmonary disease (COPD) when criteria 1 **or** 2 are met:
   1. Palliative use for individuals with advanced COPD and an active advance directive not to intubate; **or**
   2. Persistent hypercapnia with a $PaCO_2$ level of 53 mm Hg or greater on room air;

   or
C. Obesity Hypoventilation Syndrome (OHS) when criteria 1 **and** 2 are met:
   1. OHS is diagnosed based on ALL of the following (a, b, **and** c):
      a. Body mass index (BMI) is greater than or equal to 30 kg/m^2; **and**
      b. Sleep-disordered hypoventilation has been documented by polysomnography and other conditions are not considered the sole cause of hypoventilation. Examples include, but are not limited to: neuromuscular or restrictive thoracic disease (see criterion A above), COPD (see criterion B above), interstitial lung disease, pleural restriction, hypothyroidism, or medications; **and**
      c. Hypoventilation is documented with an awake $PaCO_2$ level greater than or equal to 45 mm Hg; **and**
   2. CPAP or BiPAP treatment is not appropriate as evidenced by any of the following (a, b **or** c):
      a. OSA is not present as confirmed by polysomnography with an apnea/hypopnea index (AHI) less than 5; **or**
      b. Hypoventilation was not corrected with CPAP or BiPAP titration as evidenced by persistence of an awake $PaCO_2$ level greater than 45 mm Hg after 3 months of compliant use of CPAP or BiPAP; **or**
      c. Individuals started on NPPV therapy as OHS treatment during hospitalization can continue for up to 3 months of home therapy to provide time to complete outpatient CPAP or BiPAP titration.

Continuing use:

Continuing use of NPPV therapy with a home ventilator is considered **medically necessary** when **BOTH** of the following are met (A **and** B):

A. Documentation of compliant use must be reported every 3 months; **and**
B. The device monitor documents compliant use for an average of 4 or more hours per 24 hours **and** the requesting physician documents ongoing benefit from its use.

Not Medically Necessary:

Home use of NPPV therapy *with a home ventilator* is considered **not medically necessary** when the above criteria are not met and for all other conditions, including but not limited to: chronic stable COPD without hypercapnia, **and** central sleep apnea of heart failure.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
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 [when specified as used with a non-invasive interface]

ICD-10 Diagnosis

	All diagnoses, including, but not limited to, the following:
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E84.0	Cystic fibrosis with pulmonary manifestations
G12.20-G12.9	Motor neuron disease
J44.0-J44.9	Other chronic obstructive pulmonary disease
J96.00-J96.92	Respiratory failure, not elsewhere classified
M95.4	Acquired deformity of chest and rib
Q67.6	Pectus excavatum
Q67.8	Other congenital deformities of chest
Q76.8-Q76.9	Other/unspecified congenital malformations of bony thorax
Z99.11	Dependence on respirator [ventilator] status

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Noninvasive positive pressure ventilation therapy (NPPV) uses a mechanical ventilator with a face or nasal mask interface to deliver pressurized air or a gaseous mix to the individual with or without preset rates and volumes. In general, these devices have provided benefit when used intermittently in the treatment of conditions associated with ventilatory compromise or failure resulting in hypercapnia (CO_2 retention) and hypoxemia (insufficient oxygenation of circulating arterial blood). This may result from restrictive and/or obstructive ventilatory impairments. Common causes include:

- lung disease, such as chronic obstructive pulmonary disease (COPD) or cystic fibrosis;
- thoracic cage abnormalities, such as severe kyphoscoliosis or following thoracoplasty;
- neuromuscular disorders affecting the muscles of respiration, for example amyotrophic lateral sclerosis (ALS); and
- obesity hypoventilation syndrome, which is characterized by the triad of obesity (body mass index$\geq$ 30 kg/m^2), daytime hypercapnia (arterial carbon dioxide tension ≥ 45 mm Hg) and sleep disordered breathing, after ruling out other disorders that may cause alveolar hypoventilation.

A systematic review and data meta-analysis, conducted in 2002 and updated in 2012, assessed the effects of nocturnal NPPV administered at home via a nasal or facial mask for 245 hypercapnic subjects with stable COPD. Seven studies evaluated the effects of nocturnal NPPV when used at home for 3 and 12 month durations. The studies evaluated the effects of this treatment on the partial pressure of CO2 and O2 in arterial blood, 6-minute walking distance (6MWD), health-related quality of life (HRQoL), forced expiratory volume in one second (FEV1), forced vital capacity (FVC), maximal inspiratory pressure (PImax) and sleep efficiency. Results for nocturnal NPPV delivered at home for at least 3 months showed no consistent clinically significant or statistically significant effect on gas exchange, exercise tolerance, HRQoL, lung function, respiratory muscle strength or sleep efficiency. Meta-analysis of the two long-term studies with 12-month data reflected no significant improvements in blood gases, HRQoL or lung function after 12 months of NPPV. The small sample size of these studies precluded definitive conclusions. Although this analysis was limited, the authors summarized the findings to report that NPPV therapy in stable COPD demonstrated little or no difference in clinical outcomes, and further study is needed (Struik, 2014).

The GOLD Report (Global Initiative for Chronic Obstructive Lung Disease) was initiated in 1998 with the goal to provide recommendations for the management of COPD, based on the best scientific information available. This large ongoing project, created with cooperation from the National Heart, Lung and Blood Institute; the National Institutes of Health and the World Health Organization, has been reviewed and updated on a regular basis with the focus on diagnosis, assessment and treatment for COPD. Based on the critical review of the most current published evidence by members of the GOLD Science Committee, recommendations regarding state-of-the-art management of COPD have been reissued, as warranted in the science. In 2019, the GOLD Report provided the following recommendations for NPPV in COPD:

- In patients with severe chronic hypercapnia and history of hospitalizations for acute respiratory failure, long-term noninvasive ventilation may decrease mortality and prevent re-hospitalization.
- Whether to use NPPV chronically at home to treat patients with acute or chronic respiratory failure following hospitalization remains undetermined and outcomes may be affected by persistent hypercapnia.
- NPPV may improve hospitalization-free survival in select patients after recent hospitalization particularly in those with pronounced daytime persistent hypercapnia ($PaCO_2$ > 52 mm Hg.) (LOE:B).
- Noninvasive mechanical ventilation should be the first mode of ventilation used in COPD patients with acute respiratory failure who have no absolute contraindication because it improves gas exchange, reduces the work of breathing and the need for intubation, decreases hospitalization duration and improves survival (LOE: A)…Mortality and intubation rates are reduced by this intervention.
- Indications for noninvasive mechanical ventilation include at least ONE of the following:
    - Respiratory acidosis ($PaCO_2$ > 6.0 kPa or 45 mm Hg. and arterial pH < 7.35).
    - Severe dyspnea with signs suggestive of respiratory muscle fatigue, increased work of breathing or both, such as use of respiratory accessory muscles, paradoxical motion of the abdomen, or retraction of the intercostal spaces.
    - Persistent hypoxemia despite supplemental oxygen therapy (GOLD, 2019).

The recommendations of the 2019 GOLD report were based on the results of a randomized controlled trial of 116 subjects with persistent hypercapnia ($PaCO_2$ > 53mm Hg) 2 weeks to 4 weeks after resolution of respiratory acidemia, who were recruited from 13 UK centers between 2010 and 2015 to receive either home oxygen therapy alone or home oxygen plus NPPV. It is noted that the NPPV was initiated using a “high pressure strategy” with mean inspiratory pressure of 24 cm H_2O and expiratory pressure of 4 cm H_2O. The primary outcome of time to readmission or death within 12 months was significantly improved for the home oxygen therapy plus home NPPV group, with the median time to readmission or death of 4.3 months, compared with 1.4 months in the home oxygen therapy alone group. The difference in the estimated 1-year risk of readmission or death was 17.0% (63.4% in the home oxygen plus home NPPV group vs. 80.4% in the home oxygen alone group, adjusted hazard ratio of 0.49 (95% confidence interval [CI], 0.31-0.77; p=0.002). At 12 months, 16 subjects had died in the home oxygen plus home NPPV group vs. 19 in the home oxygen alone group. The authors

concluded that the addition of home NPPV to home oxygen “Should be considered” in the setting of severe COPD with persistent hypercapnia after a life-threatening exacerbation (Murphy, 2017).

In 2014, Köhnlein and colleagues conducted a prospective, randomized controlled trial that compared NPPV with standard treatment for 195 subjects with stable GOLD stage IV COPD and a $PaCO_2$ of 7 kPa (51.9 mm Hg) or higher and a pH higher than 7.35. All subjects from the control group and the NPPV group were included in the primary analysis. At 1 year, mortality was 12% (12 of 102 subjects) in the intervention group and 33% (31 of 93 subjects) in the control group; with hazard ratio 0-24 (95% CI, 0.11–0.49; p=0.0004). The only intervention-related adverse event reported by 14 (14%) of trial participants was facial skin rash, which could be managed by changing the type of mask. The authors concluded that the addition of NPPV to standard treatment improves survival in individuals with hypercapnic stable COPD when the NPPV is targeted to greatly reduce hypercapnia, (that is, mean pressure, 21.6 cm H_2O inspiratory and 4.8 cm H_2O expiratory to achieve a 20% reduction in the $PaCO_2$).

Many ventilator devices have obtained clearance from the U.S. Food and Drug Administration (FDA) as class II devices used to provide ventilator support for a variety of conditions. On March 13, 2009 the Trilogy100 Ventilatory Support System (Philips Healthcare, Andover MA; formerly Respironics, Inc., Monroeville, PA), a portable ventilator device, obtained FDA 510(k) clearance for the following indications:

> The Respironics Trilogy l00 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy100 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.). The device is intended to be used in home, institution/hospital, and portable applications, such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation. It is not intended to be used as a transport ventilator (FDA, 2009).

This FDA clearance considers the Trilogy100 system substantially equivalent to other predicate devices currently marketed and includes ventilator devices with the capability to adjust delivery features, such as tidal volume, pressure and backup rate control.

According to Philips Respironics, the Trilogy series of ventilators includes devices with patented AVAPS™ (Average Volume Assured Pressure Support) technology, described as follows:

> AVAPS-AE is a bi-level therapy mode that automatically adjusts Expiratory Positive Airway Pressure (EPAP), pressure support, and the backup breath rate. AVAPS-AE automatically adjusts EPAP to maintain a patent airway. It also monitors delivered tidal volume and adjusts pressure support accordingly to provide the average target tidal volume. AVAPS-AE has the ability to maintain a backup breath rate* based on the patient's own spontaneous breathing rate (Philips Healthcare/Respironics, Inc.).

***Note:** *This document addresses NPPV therapy with BiPAP devices that are capable of delivering back-up rate support/control, when the back-up rate support feature is needed, in order to ensure adequate respiratory function. One such device is the Trilogy100 ventilatory system.*

Respiratory assist devices are covered by the Center for Medicare and Medicaid (CMS) under the Durable Medical Equipment benefit. According to the CMS Administrative Carrier policy for durable medical equipment (DME MAC):

> Noninvasive positive pressure respiratory assistance provided by a respiratory assist device, (that is, a ventilator), is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the usage of more invasive airway access (for example, a trachea tube via a tracheostomy). It may be applied to assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is to be distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of ventilatory support would lead to the imminent demise of the patient (CMS, 2002).

According to the American Thoracic Society (ATS) clinical practice guideline, Evaluation and Management of Obesity Hypoventilation Syndrome, OHS is a condition defined by:

> The combination of obesity (body mass index [BMI] $\geq$ 30 kg/m^2), sleep-disordered breathing (SDB), and awake daytime hypercapnia (awake resting $PaCO_2 \geq 45$ mm Hg at sea level), after excluding other causes for hypoventilation. OHS is the most severe form of obesity-induced respiratory compromise and leads to serious sequelae, including increased rates of mortality, chronic heart failure, pulmonary hypertension, and hospitalization, due to acute-on-chronic hypercapnic respiratory failure, among others (Mokhlesi, 2019).

The ATS multidisciplinary panel of experts conducted a full systematic review of the literature, in order to make the following recommendations:

- Stable ambulatory individuals diagnosed with OHS should receive positive airway pressure therapy, (that is continuous PAP [CPAP] or bilevel PAP [BiPAP]) during hours of sleep.
- Individuals with symptomatic OHS who have significant comorbidities and those with chronic respiratory failure after an episode of acute-on-chronic hypercapnic respiratory failure may particularly benefit from using PAP.
- Approximately 90% of individuals with OHS have coexistent OSA, which is defined by an apnea–hypopnea index (AHI) greater than 5 events/hour, with nearly 70% having severe OSA (AHI greater than 30 events/hour).
- PAP therapy has become the primary management option for controlling SDB and reversing awake hypoventilation in persons with OHS.
- The ATS guideline recommends initiating first-line treatment with CPAP, rather than NPPV, in stable ambulatory persons diagnosed with OHS and concomitant severe OSA.
- When CPAP/BiPAP fail to correct the hypoventilation, nocturnal home therapy with NPPV is recommended (Mokhlesi, 2019).

The ATS recommendation for use of CPAP or BiPAP during sleep hours as first-line treatment for the majority of persons with stable OHS is based on limited available studies. These have demonstrated that, although CPAP does not increase alveolar ventilation, it can improve awake respiratory failure by facilitating the unloading of CO_2 accumulated during complete or partial airflow obstruction during sleep.

The Pickwick Study (Masa, 2015) followed 221 individuals with OHS in a prospective, randomized, unblinded trial comparing use of CPAP during sleep, use of volume-targeted non-invasive ventilatory (NIV) support during sleep and awake periods, and lifestyle modification. The study enrolled subjects with severe OHS, defined as obesity (BMI ≥ 30), stable daytime hypercapnia ($PaCO_2 \geq 45$ mm Hg, pH > 7.35, no clinical worsening during the previous 2 months) and the absence of other conditions related to daytime hypercapnia. The lifestyle modification group received instructions about a 1000-calorie diet, sleep hygiene, avoidance of drugs affecting sleep (including caffeine, alcohol and tobacco), and supplemental oxygen if needed. The CPAP and NIV groups also

received lifestyle modification instructions and supplemental oxygen if needed. CPAP was provided at fixed levels. NIV was provided as bilevel pressure with assured volume support. Outcomes were assessed at baseline and after 1 and 2 months of participation. The primary outcome was room air $PaCO_2$ assessed by arterial blood gas. Secondary outcomes included anthropomorphic measures, symptom intensity, sleepiness measured with the Epworth Scale (ESS), quality-of-life measures, polysomnography, spirometry, 6-minute walk distance (6MWD), and other arterial blood gas measures. The study found that the $PaCO_2$ improved in all 3 groups (-5.5 for NIV, -3.7 for CPAP, and -3.2 for lifestyle modification) but the only statistically significant difference in improvement was between the NIV and lifestyle modification groups. NIV produced a statistically significant change between baseline and 2 months for forced vital capacity (FVC) and 6MWD while the other interventions did not. The difference in FVC and 6MWD improvement between the NIV group and the CPAP group was not significant. There were no significant differences in changes to sleepiness, quality-of-life, or weight. NIV and CPAP were both better than lifestyle modification alone in improving polysomnography results and clinical symptoms, but the difference between NIV and CPAP was not significant. The investigators found that NIV or CPAP adherence for more than 4 hours/day was associated with more significant changes in daytime $PaCO_2$.

The authors of the Pickwick Study theorized that CPAP is not itself a treatment for daytime hypercapnia, but that reducing the number of nocturnal obstructive apneas could explain the reduction in daytime CO_2 associated with CPAP treatment in this study. Because they could not theorize another mechanism for daytime CO_2 reduction, they did not assign subjects with low AHI values to treatment with CPAP.

The Spanish Sleep Network reported longer-term results for the NIV and CPAP cohorts of the Pickwick Study in 2019 (Masa, 2019). The median follow-up was 5.44 years. The investigators did not find a statistically significant between-group difference during this period for the primary outcome of hospitalization days for any cause or for the secondary outcomes of hospital admissions, emergency visits, ICU admissions, cardiovascular events or mortality. The authors note that priori power estimations were not done for the secondary measures, and the results for these outcomes need additional study for confirmation. The authors concluded that, “Non-invasive ventilation and continuous positive airway pressure seem to have similar long-term effectiveness.”

In 2017, Orfanos and colleagues conducted a small prospective pilot study of 15 stable subjects with OHS and moderate to severe concomitant OSA but without obstructive pulmonary disease. Measurements were taken, first while on NPPV for more than 2 months and after being switched to CPAP. There were no significant differences for pooled data in diurnal alveolar blood gases, nocturnal capnometry (p=0.534), nocturnal oximetry (p=0.218), mean compliance (p=0.766), mean AHI (p=0.334), quality of life or quality of sleep. It was noted that, (of the 15 individuals who completed the study), 80% favored CPAP over NPPV. The authors concluded that use of CPAP in stable OHS resulted in similar efficacy for diurnal and nocturnal alveolar gas exchange, quality of life and quality of sleep. These findings need further confirmation in larger trials with longer term outcomes data. Individuals presenting with a greater degree of initial ventilatory failure, worse lung function, advanced age, or less severe OSA may be less likely to respond to CPAP.

In 2017, Howard and colleagues conducted a multicenter, parallel, double-blind trial for initial treatment of OHS, with participants randomized to nocturnal BiPAP or CPAP for 3 months. Of the initial 60 participants, 57 completed follow-up and were included in analysis (mean age 53 years, BMI 55 kg/m_2, $PaCO_2$ 60 mm Hg). There was no difference in treatment failure between groups (BiPAP - 14.8% vs. CPAP - 13.3%; p=0.87). Treatment adherence and awake $PaCO_2$ values were similar after 3 months (5.3 hours/night for BiPAP, 5.0 hours/night for CPAP, p=0.62; $PaCO_2$ 44.2 and 45.9 mm Hg, respectively; p=0.60). Between-group differences were not significant for improvement in sleepiness (ESS 0.3 [95% CI; 2.8, 3.4]; p=0.86) and health-related quality of life (HRQoL) using a questionnaire (Short Form [SF] 36-SF6d 0.025 [95% CI; -0.039, 0.088]; p=0.45). Baseline severity of ventilatory failure ($PaCO_2$) was the only significant predictor of persistent ventilatory failure at 3 months (OR 2.3; p=0.03). The authors concluded that in newly diagnosed severe OHS, BiPAP and CPAP resulted in similar improvements in ventilatory failure, HRQoL and adherence. Baseline $PaCO_2$ predicted persistent ventilatory failure to treatment with BiPAP and CPAP.

Definitions

Central sleep apnea (CSA): Refers to periods during sleep when normal airflow to and from the lungs is absent resulting in abnormally low levels of PaO_2 in arterial blood due to inadequate respirations.

Chronic obstructive pulmonary disease (COPD): Any disorder that persistently obstructs bronchial airflow and mainly involves two related diseases -- chronic bronchitis and emphysema. Both cause chronic obstruction of airflow through the airways and in and out of the lungs. COPD is generally permanent and progresses (becomes worse) over time. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD, 2019 Report), the stages of COPD are defined as follows:

- Stage 1: Very mild COPD with a FEV_1 about 80 percent or more of normal.
- Stage 2: Moderate COPD with a FEV_1 between 50 and 80 percent of normal.
- Stage 3: Severe emphysema with FEV_1 between 30 and 50 percent of normal.
- Stage 4: Very severe COPD with a lower FEV_1 than Stage 3, or those with Stage 3 FEV_1 and low blood oxygen levels.

Forced expiratory volume (FEV_1): The volume of oxygen expressed during expiration in 1 second. FEV_1 is a marker used to monitor lung function and severity of lung disease, such as COPD.

Fractional concentration of oxygen (FIO_2): The concentration of oxygen delivered for inspiration. The usual FIO_2 refers to the oxygen concentration in normal breaths when on room air (that is, without oxygen supplementation).

Forced vital capacity (FVC): The amount of air that can be forcibly exhaled from the lungs after taking the deepest breath possible. Measurements of the FVC are useful in distinguishing obstructive from restrictive lung disease.

Home ventilator: A VENTILATOR device used in the home.

Hypercapnia (also referred to as hypoventilation): Refers to an elevation in the arterial carbon dioxide tension ($PaCO_2$). The carbon dioxide (CO_2) level in arterial blood is directly proportional to the rate of carbon dioxide (VCO_2) production and inversely proportional to the rate of CO_2 elimination by the lung (referred to as alveolar ventilation).

Invasive positive pressure ventilation support (IPPV): This is another form of ventilator support that is distinguished from noninvasive positive pressure ventilator support (see below), in that the pressurized oxygen is administered directly into the trachea via a securely intubated airway or tracheostomy tube. The use of IPPV is not addressed in this document.

Minute ventilation: The number of breaths per minute times the volume of each breath.

Neuromuscular disease (also referred to as neuromuscular disorders): Refers to multiple conditions that impair the functioning of

various nerves of the peripheral nervous system, including motor and sensory nerves, and also affects communication between nerves and muscles resulting in wasting and weakness of muscles. One such neuromuscular disease is amyotrophic lateral sclerosis (ALS) which is a progressive nervous system disease that attacks the nerve cells of the brain and spinal cord with resultant degeneration of motor neurons and progressive muscle weakness and atrophy with loss of muscle function.

Nocturnal hypoventilation (also referred to as nocturnal hypoxemia): Refers to a respiratory condition where inadequate gaseous exchange during sleep results in abnormally high CO_2 in arterial blood, which is also known as CO_2 retention.

Noninvasive positive pressure ventilation support (NPPV): A device that delivers pressurized air to the individual through a facemask or nasal interface tightly sealed to the face. Supplemental oxygen may be added to the pressurized air.
NPPV may be provided through several modes including:

- Automated Positive Airway Pressure (APAP): air is supplied at an automatically-adjusting pressure based on an individual's needs.
- Bi-level Positive Airway Pressure (BiPAP): air is supplied at a higher pressure during inspiration and lower pressure during expiration. Some BiPAP devices are equipped with a back-up rate support feature that ensures the individual will receive a preset minimum number of breaths per minute. The term BiPAP is a registered trademark of Respironics, Inc., but is widely used to describe any bi-level positive airway pressure device currently marketed.
- Continuous Positive Airway Pressure (CPAP): air is supplied at a constant pressure throughout the respiratory cycle.
- Non-invasive Ventilator: a VENTILATOR used with a facemask or nasal interface tightly sealed to the face.

Pressure support: Provision of pressurized air with or without supplemental oxygen at a specified inspiratory pressure or with a set level of positive end-expiratory pressure (PEEP). Inspiration ends when the preset inspiratory pressure is achieved.

Rate support: Provision of pressurized air with or without supplemental oxygen at a specified minimum number of breaths per minute.

Partial pressure of oxygen (also known as PaO_2): A measurement of oxygen in arterial blood.

Partial pressure of carbon dioxide (also known as $PaCO_2$): A measurement of carbon dioxide in arterial blood.

Respiratory failure, acute or chronic: A respiratory disorder where insufficient oxygenation, insufficient alveolar ventilation, or both, are experienced by the individual in his/her attempts to breathe. Chronic respiratory failure is associated with certain conditions, such as chronic obstructive pulmonary disease (COPD) which, over time or emergently, may progress to acute respiratory failure (ARF) which is life threatening.

Restrictive thoracic disorders: Refers to a variety of neuromuscular and anatomical anomalies of the chest/rib cage area that may result in hypoventilation, particularly during sleep. Nocturnal hypoventilation is associated with a host of health hazards and can also significantly impact the quality of life. The use of mechanical NPPV devices has been found helpful in reducing the episodes of nocturnal hypoventilation and the associated complications for a significant number of those who are able to tolerate the therapy.

Sleep-disordered breathing (SDB): Abnormalities of respiration during sleep. Episodes often result in reductions in blood oxygen saturation and are usually terminated by brief arousals from sleep. This common disorder often results in oxidative stress and inflammation and is associated with multiple age-related health disorders.

Sleep-related hypoventilation: A condition is identified for adults when the arterial PCO_2 (or surrogate) during sleep is > 55 mm Hg for ≥ 10 minutes or there is an increase in the arterial PCO_2 (or surrogate) during sleep of ≥ 10 mm Hg (in comparison to an awake supine value) to a value exceeding 50 mm Hg for ≥ 10 minutes. For pediatric subjects, sleep-related hypoventilation is identified when the arterial PCO_2 (or surrogate) is > 50 mm Hg for > 25% of total sleep time.

Ventilator: A mechanical device capable of providing pressurized air with or without supplemental oxygen and two or more of the following features: pressure support, rate support, volume support or various combinations of pressure, rate, and volume support.

Volume support: Provision of pressurized air with or without supplemental oxygen at a specified tidal volume. Inspiration ends when a preset tidal volume or minute ventilation is achieved.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Revised	05/12/2022	MPTAC review. The MN criteria for NPPV in neuromuscular disease were revised to add maximum inspiratory pressure of less than or equal to 60 mm H_2O. The MN criteria for NPPV in persistent hypercapnic end-stage COPD have been revised to remove the requirement for PaO_2 level and for NPPV therapy without the rate support feature the O_2 saturation range requirement has been removed. Deleted the words, “for adults” from the MN statement for home NPPV therapy. The Definitions and References sections were updated.
Reviewed	05/13/2021	MPTAC review. Updated References section. Reformatted Coding section.
Revised	05/14/2020	MPTAC review. The indication of OHS was added to the MN indications for NPPV when criteria are met. The Discussion, Coding and References sections were updated.
New	08/22/2019	MPTAC review. Initial document development.
