

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) or the Obesity Hypoventilation Syndrome;
- Through a tracheostomy.

Clinical Indications

Medically Necessary:

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

- A. The primary cause of respiratory failure is neuromuscular disease (for example, amyotrophic lateral sclerosis) or restrictive thoracic disease (for example, thoracic cage abnormalities) **and** an arterial blood gas PaCO₂ level is greater than or equal to 45 mm Hg while awake and breathing the individual's usual FIO₂;
- 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. BOTH of the following criteria (a) **and** (b) are met:

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Noninvasive Home Ventilator Therapy for Respiratory Failure

- a) Persistent hypercapnia with a PaCO₂ level of 53 mm Hg or greater and a PaO₂ level less than 55 mm Hg on room air; **and**
- b) Treatment without the rate support feature does not maintain the oxygen saturation above 88% without driving the PaCO₂ level to 60 mm Hg or greater.

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.

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

- E84.0 Including, but not limited to, the following:
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

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Noninvasive Home Ventilator Therapy for Respiratory Failure

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

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 been shown to provide benefit when used intermittently in the treatment of conditions associated with ventilatory compromise or failure resulting in hypercapnia (CO₂ 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; and neuromuscular disorders affecting the muscles of respiration, for example amyotrophic lateral sclerosis (ALS).

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, six-minute walking distance (6MWD), health-related quality of life (HRQoL), forced expiratory volume in one second (FEV₁), forced vital capacity (FVC), maximal inspiratory pressure (P_Imax) and sleep efficiency. Results for nocturnal NPPV delivered at home for at least three 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:

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Noninvasive Home Ventilator Therapy for Respiratory Failure

- 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 outcome 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 ($\text{PaCO}_2 \geq 52$ 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 ($\text{PaCO}_2 \geq 6.0$ 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 ($\text{PaCO}_2 > 53$ mm 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 H₂O and expiratory pressure of 4 cm H₂O. 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% CI, 0.31-0.77; p=.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% Confidence interval [CI] 0.11–

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Noninvasive Home Ventilator Therapy for Respiratory Failure

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 H₂O inspiratory and 4.8 cm H₂O expiratory to achieve a 20% reduction in the PaCO₂).

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 Trilogy100 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 CMS under the Durable Medical Equipment benefit. According to the Center for Medicare and Medicaid Services (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

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Noninvasive Home Ventilator Therapy for Respiratory Failure

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).

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 PaO₂ 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 air flow 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 FEV₁ about 80 percent or more of normal.

Stage 2: Moderate COPD with a FEV₁ between 50 and 80 percent of normal.

Stage 3: Severe emphysema with FEV₁ between 30 and 50 percent of normal.

Stage 4: Very severe COPD with a lower FEV₁ than Stage 3, or those with Stage 3 FEV₁ and low blood oxygen levels.

Forced expiratory volume (FEV₁): The volume of oxygen expressed during expiration in 1 second. FEV₁ is a marker used to monitor lung function and severity of lung disease, such as COPD.

Fractional concentration of oxygen (FIO₂): The concentration of oxygen delivered for inspiration. The usual FIO₂ 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 (PaCO₂). The carbon dioxide (CO₂) level in arterial blood is directly proportional to the rate of carbon dioxide (VCO₂) production and inversely proportional to the rate of CO₂ elimination by the lung (referred to as alveolar ventilation).

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Noninvasive Home Ventilator Therapy for Respiratory Failure

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 CO₂ in arterial blood, which is also known as CO₂ retention.

Noninvasive positive pressure ventilation support (NPPV): A device which delivers pressurized air to the individual through a face mask 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 face mask 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.

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Noninvasive Home Ventilator Therapy for Respiratory Failure

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 PaO₂): A measurement of oxygen in arterial blood.

Partial pressure of carbon dioxide (also known as PaCO₂): 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.

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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Websites for Additional Information
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Index

Bi-lateral positive airway pressure (BiPAP)
 Mechanical Ventilation
 Non-Invasive Positive Pressure
 Noninvasive Respiratory Assist Devices

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Noninvasive Home Ventilator Therapy for Respiratory Failure

Positive Pressure Respiratory Assist Devices
 S9 VPAP™ ST-A with iVAPS, ResMed
 Trilogy100, Philips Healthcare (formerly Respirationics)
 Trilogy200, Philips Healthcare (formerly Respirationics)
 Ventilator, Continuous, Non-life supporting
 Ventilators, Home use
 VPAP™ COPD, ResMed

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
New	08/22/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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