

Home Mechanical Ventilation Devices

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Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Criteria

E0465 (Home ventilator, any type, used with invasive interface (e.g., tracheostomy tube))

A home ventilator (HCPCS E0465) is considered medically necessary for an individual with respiratory failure when **all** the following criteria are met:

- The individual has documentation of a medical condition including **any** of the following:
 - obstructive pulmonary condition(s) (e.g., severe Chronic Obstructive Pulmonary Disease (COPD) with hypercapnia, cystic fibrosis, or bronchiectasis)
 - neuromuscular or neurologic condition(s)
 - restrictive pulmonary condition(s)
 - obesity hypoventilation syndrome (OHS)
 - other medical condition causing chronic hypoventilation
 - chronic lung disease of infancy, including bronchopulmonary dysplasia
 - obstructive sleep apnea in a pediatric individual
- CPAP or BiPAP treatment is not appropriate as indicated by **any** of the following:
 - CPAP or BiPAP was ruled out due to clinical severity.
 - CPAP or BiPAP was trialed and found ineffective (ie. persistent hypercapnia, intolerable symptoms).
 - settings or functionality required by the individual could not be provided with CPAP or BiPAP.
 - CPAP or or BiPAP device does not meet minimum body requirements.

- alarms required by the individual are not available on bilevel positive pressure respiratory assistance device for the individual.
- Respiratory status is stable.
- The home environment is safe for ventilator use.
- A trained caregiver(s) is available to assist with ventilator use.

E0466 (Home ventilator, any type, used with non-invasive interface (e.g., mask, chest shell))

A home ventilator (HCPCS E0466) is considered medically necessary for an individual with respiratory failure when **all** the following criteria are met:

- The individual has documentation of a medical condition including **any** of the following:
 - obstructive pulmonary condition(s) (e.g., severe Chronic Obstructive Pulmonary Disease (COPD) with hypercapnia, cystic fibrosis, or bronchiectasis)
 - neuromuscular or neurologic condition(s)
 - restrictive pulmonary condition(s)
 - obesity hypoventilation syndrome (OHS)
 - other medical condition causing chronic hypoventilation
 - chronic lung disease of infancy, including bronchopulmonary dysplasia
 - obstructive sleep apnea in a pediatric individual
- CPAP or BiPAP treatment is not appropriate as indicated by **any** of the following:
 - CPAP or BiPAP was ruled out due to clinical severity.
 - CPAP or BiPAP was trialed and found ineffective (ie. persistent hypercapnia, intolerable symptoms).
 - settings or functionality required by the individual could not be provided with CPAP or BiPAP.
 - CPAP or or BiPAP device does not meet minimum body requirements.
 - alarms required by the individual are not available on bilevel positive pressure respiratory assistance device for the individual.
- Respiratory status is stable (i.e., the individual is able to protect the airway and clear secretions).
- The home environment is safe for ventilator use.

HCPCS E0647 (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)

A multi-function home ventilator (HCPCS E0467) is considered medically necessary when general coverage criteria for a standard home ventilator are met and the documentation supports a management plan requiring **any** of the following devices:

- oxygen concentrator
- cough stimulator
- suction pump
- nebulizer

Initial Rental Timeframe

- Initial rental timeframe is **twelve (12) months**.

Continued Use

The continued use of a home ventilator for up to an additional twelve (12) months rental is indicated when there is documentation of **both** the following:

- The individual has been re-evaluated by the treating practitioner.
- There is documentation of continued benefit and medical need.

Additional Information

A primary and a secondary ventilator may be considered if each is serving a different medical or functional purpose.

Examples of indicated scenarios including, but not limited, to **any** of the following:

- One type of ventilator (e.g., a negative pressure ventilator with a chest shell) is required for part of the day and a different type of ventilator (e.g., positive pressure ventilator with a nasal mask) is required during the rest of the day.
- A portable ventilator is mounted on the wheelchair for use during the day and individual requires a stationary ventilator for use while in bed.
- The individual lives in an area where a replacement ventilator cannot be provided within two (2) hours.

Not Medically Necessary

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 the following:

- chronic stable COPD *without* hypercapnia
- central sleep apnea of heart failure

Definitions

Term	Definition
Apnea	Cessation of airflow for at least 10 seconds.
Apnea-hypopnea index (AHI)	Average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.
Mechanical Ventilation	Mechanical ventilation is an artificial means of respiratory support to partially or fully assist respirations and gas exchange. The primary goal of mechanical ventilation in individuals with respiratory failure is to maintain adequate alveolar ventilation and arterial blood oxygen content, preventing respiratory acidosis and hypoxia. Mechanical ventilation can be delivered invasively via a tracheostomy or noninvasively via a nasal, oronasal, or facial mask.
Noninvasive positive pressure ventilation support (NIPPV)	The delivery of mechanical ventilation noninvasively via a nasal, oronasal, or facial mask.
Bi-level Positive Airway Pressure (BiPAP)	Air is supplied at a higher pressure during inspiration and lower pressure during expiration.
Continuous Positive Airway Pressure (CPAP)	Air is supplied at a constant pressure throughout the respiratory cycle.
Hypercapnia (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).
Partial pressure of oxygen (also known as PaO_2)	A measurement of oxygen in arterial blood.

Term	Definition
Partial pressure of carbon dioxide (also known as PaCO₂)	A measurement of carbon dioxide in arterial blood.
Average Volume Assured Pressure Support: (AVAPS-AE)	AVAPS-AE is a bi-level therapy mode used with the FDA-approved Trilogy series of devices 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 individual's own spontaneous breathing rate.

Evidence Discussion

Mechanical ventilation is a means of artificial support to assist with respirations¹ and gas exchange. These ventilators can provide assistance through a face mask, or endotracheal or tracheostomy tubes. The primary goal is to maintain adequate ventilation and blood oxygen content.

Noninvasive positive pressure ventilation (NPPV) is the delivery of mechanical ventilation through a noninvasive interface (such as a tight-fitting mask) using a bilevel positive airway pressure (BiPAP) or home mechanical ventilation (HMV) device. 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.² NPPV may improve hospitalization-free survival in select individuals after recent hospitalization, particularly in those with pronounced daytime persistent hypercapnia.^{2,3} A systematic review and meta-analysis that included over 50,000 individuals evaluated mortality, all-cause hospital admissions, and quality of life in hypercapnic chronic obstructive pulmonary disease (COPD) individuals treated with

¹ Pearson et al. Management of Respiratory Failure: Ventilator Management 101 and Noninvasive Ventilation. *Clin J Am Soc Nephrol* 2022. 17(4):572-80.

² National Heart, Lung and Blood Institute of the United States; National Institutes of Health and the World Health Organization. Global Initiative for Chronic Obstructive Lung Disease Report (GOLD). Updated 2023. https://goldcopd.org/wp-content/uploads/2023/03/GOLD-2023-ver-1.3-17Feb2023_WMV.pdf

³ Murphy et al. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *J of the Am Med Association* 2017. 317(21):2177-86.

NPPV vs standard care found that use of mechanical ventilation was associated with significantly fewer all-cause hospital admissions.⁴

The American Thoracic Society conditionally recommends nocturnal noninvasive ventilation (NIV) BiPAP for individuals with chronic hypercapnic respiratory failure due to COPD who are not in an acute exacerbation.⁵

The American Association of Respiratory Care recommends provision of backup ventilators for individuals who cannot maintain spontaneous ventilation for 4 or more consecutive hours as well as for individuals who live in an area where a replacement ventilator cannot be provided within 2 hours.⁶

The American College of Chest Physicians, the American Association for Care, the American Academy of Sleep Medicine, and the American Thoracic Society suggest that, for individuals with restrictive respiratory disorders who have progressed to the use HMV for more than 18 hours a day, a second device should be offered and at least 1 of the 2 devices should be portable so that wheelchair attachment and mobility are possible.

Codes

HCPCS	Description
E0465	Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube)
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

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- 4 Wilson ME, et al. Association of home noninvasive positive pressure ventilation with clinical outcomes in chronic obstructive pulmonary disease: a systematic review and meta-analysis. *J of the Am Med Association* 2020;323(5):455-465
- 5 Macrea et al. Long-Term Noninvasive Ventilation in Chronic Stable Hypercapnic Chronic Obstructive Pulmonary Disease. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med* 2020. 202(4):e74-e87.
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