Home Ventilators

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### Related Coverage Resources

- Airway Clearance Devices in the Ambulatory Setting
- Obstructive Sleep Apnea Treatment Services
- Respiratory Services and Supplies Reimbursement policy (R15)
- Ventilator Weaning

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**INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Overview

This Coverage Policy addresses in-home ventilators HCPCS E0465-E0467 only.

### Coverage Policy

Coverage for Durable Medical Equipment (DME), including in-home ventilators varies across plans. Please refer to the customer’s benefit plan document for coverage details.

**INVASIVE INTERFACE (HCPCS E0465)**

If coverage for a home ventilator with invasive interface (e.g., tracheostomy tube) is available, **BOTH** of the following conditions of coverage apply:

- Individual has ONE of the following conditions:
  - a neuromuscular disease
  - a thoracic restrictive disease
  - chronic respiratory failure consequent to chronic obstructive pulmonary disease
  - congenital central hypoventilation syndrome
  - chronic lung disease of infancy (e.g., bronchopulmonary dysplasia)
  - obesity hypoventilation syndrome
➢ restrictive disorder of chest wall

• There is a safe physical environment as determined by the patient’s discharge planning team including adequate resources for care in the home

NON-INVASIVE INTERFACE (HCPCS E0466)
If coverage for a home ventilator with non-invasive interface (e.g., facemask) is available, **ALL** of the following conditions of coverage apply:

• Individual has ONE of the following AND lack of ventilator support would result in a life threatening condition:
  ➢ a neuromuscular disease
  ➢ a thoracic restrictive disease
  ➢ chronic respiratory failure consequent to chronic obstructive pulmonary disease
  ➢ congenital central hypoventilation syndrome
  ➢ chronic lung disease of infancy (e.g., bronchopulmonary dysplasia)
  ➢ obesity hypoventilation syndrome
  ➢ restrictive disorder of chest wall

• Individual has demonstrated failure of bilevel positive airway pressure (BPAP) to improve hypercapnia and/or oxygen saturation level or a BPAP device is not clinically appropriate (e.g. obstructive sleep apnea).

• Individual does not require ventilation continuously (24 hours/day)

• There is a safe physical environment as determined by the patient’s discharge planning team including adequate resources for care in the home.

INVASIVE and NON-INVASIVE INTERFACE
Home ventilator devices (HCPCS E0465-E0466) are considered NOT medically necessary:

• for non-life-threatening conditions
• when used as a respiratory assistance device (RAD) including continuous positive airway pressure (CPAP), auto-titrating PAP (APAP), bilevel positive airway pressure (BPAP, BiPAP) or adaptive servo-ventilation (ASV).
• when used for treatment for obstructive sleep apnea

The Ventilation, Oxygen, Cough, Suction, Nebulization (VOCSN) multifunction ventilator (HCPCS E0467) is considered not medically necessary.

ADDITIONAL OR DUPLICATE DEVICES
Additional or duplicate home ventilator devices (HCPCS E0465-E0466) are considered medically necessary:

• for an individual who requires mechanical ventilation during mobility (e.g., for use in wheelchair) as prescribed in their plan of care
• as a secondary ventilator (serves a different purpose or is a different type of device than the individual’s primary ventilator)

Additional or duplicate home ventilator devices (HCPCS E04665-E0466) are considered NOT medically necessary and would generally NOT be covered:

• if used only as a back-up device (similar device as the individual’s primary ventilator, for multiple residences or to have in case of possible malfunction).
General Background

A ventilator, also known as a respirator, can help a person breathe when they are unable to breathe sufficiently on their own. A mechanical ventilator can take over the act of breathing completely or make breathing easier by assisting weakened respiratory muscles. Mechanical ventilation is indicated in respiratory failure, which is defined as insufficient oxygenation, insufficient alveolar ventilation, or both. The desired effect of mechanical ventilation is to maintain appropriate levels of Po2 and Pco2 in arterial blood while unloading the ventilatory muscles.

Positive Pressure Ventilation
The majority of all mechanical ventilatory support is provided by positive pressure ventilation. Positive pressure ventilators developed as a more effective breathing option to the larger, bulkier negative pressure devices (e.g., iron lung). Since the 1980s, computer technology has enabled manufacturers to produce even smaller, lightweight ventilators that are easier to transport and operate, and are better suited for people living at home. Home ventilators may be used via:
- an invasive interface (i.e., tracheostomy) or
- a noninvasive interface (i.e., nose or mouth mask, chest shell).

After careful evaluation and pulmonary function tests to assess breathing and lung function and capacity, the physician recommends a type of ventilator and appropriate interfaces. In the USA, physicians work with respiratory therapists in home health care companies that provide the equipment, supplies, and education, training and monitoring. Individuals who need to use ventilation only at night have different equipment requirements than those who need to use a ventilator around the clock. Sometimes an individual may not be comfortable with a specific ventilator or interface and may need to change them in order to find the most comfortable and effective system. Some ventilator users alternate modes and interfaces during the day and night. There are some clinical scenarios that warrant both a primary ventilator and a secondary ventilator. An example is if an individual requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) during the day and needs a different type of ventilator (e.g., positive pressure ventilator with a face mask) during the night.

Multi-mode ventilators can provide many modes of ventilation, such as pressure support, pressure control, volume control, assist/control, synchronized intermittent mandatory ventilation (SIMV), bilevel positive pressure (BiPAP, BPAP) or continuous positive airway pressure (CPAP). Examples include LTV® series (CareFusion BD), iVent 201® (GE Healthcare), Trilogy 100, 200, 202 (Philips Respironics Inc), and VOCSN Unified Respiratory System (Ventec Life Systems, Inc.).

Home ventilator, multi-function respiratory device (HCPCS E0467): The Ventilation, Oxygen, Cough, Suction, Nebulization (VOCSN) is a multifunction ventilator that can provide five therapies or a mix of therapies from a single device. Therapies provided by VOCSN include: critical care ventilation; 6 L/min oxygen concentrator; touch button cough; hospital grade suction and high performance nebulizer.

Food and Drug Administration (FDA)
Numerous positive and negative pressure ventilators are FDA-approved. One of the more recent approvals was for the VOCSN Unified Respiratory System (Ventec Life Systems, Inc., Bothell, Washington USA) which received 510(k) approval on April 7, 2017. The VOCSN Unified Respiratory System is intended to provide continuous or intermittent positive pressure ventilator support for the care of individuals who require mechanical ventilation. It may be used in invasive and noninvasive applications. The VOCSN is intended for pediatric through adult patients weighing at least 5 kg. It is intended for use in home, hospital, institutional and transport settings, including portable applications. The integral oxygen concentrator is intended for the administration of supplemental oxygen. The integral suction pump is intended for airway fluid removal and oral/ pharyngeal hygiene. The integral cough assist option is intended for patients who are additionally unable to cough or clear secretions effectively.

Literature Review
Medical Coverage Policy: 0546

Home noninvasive positive pressure ventilation (NIPPV)/ Agency for Healthcare Research and Quality (AHRQ): An Agency for Healthcare Research and Quality (AHRQ) Systematic Review was completed on Home Mechanical Ventilators. The 6/26/2018 online Draft version states 61 studies evaluating 53,414 patients were included. The purpose of the review is to evaluate home noninvasive positive pressure ventilation (NIPPV) in adults with chronic respiratory failure in terms of initiation, continuation, effectiveness, adverse events, equipment parameters and required respiratory services. Devices evaluated were home mechanical ventilators (HMV), bi-level positive airway pressure (BPAP) devices, and continuous positive airway pressure (CPAP) devices.

Key messages include:

1. In COPD, home BPAP (compared to no device) was associated with lower mortality, intubations, hospital admissions, and no change in quality of life (low to moderate Strength of Evidence [SOE]). HMV (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions (low SOE). In thoracic restrictive diseases, home HMV (compared to no device) was associated with lower mortality (low SOE). In neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life (low SOE).

2. Current comparative evidence is not available to assess the impact of many NIPPV device capabilities on patient outcomes; particularly comparing HMV to BPAP. Future comparative studies should address which device capabilities are associated with improved patient outcomes.

3. Criteria to initiate home NIPPV and home respiratory services were summarized in this report but varied and were not validated in comparative studies.

4. Incidence of non-serious adverse events such as facial rash, dry eyes, mucosal dryness, mask discomfort was around 0.3 across devices. The most commonly reported serious adverse event was acute respiratory failure. Based on direct comparisons, we found no statistically significant differences in number of treatment withdrawals or adverse events when comparing different devices or when comparing device use with no device use.

In COPD (34 studies), common criteria for NIPPV initiation were FEV1<50% normal, PaCO2 >45mmHg, pH>7.35, and/or hypoxia. BPAP (compared with no device) was associated with reductions in mortality (moderate SOE), need for intubation (moderate SOE), and hospital admissions (low SOE). HMV (compared individually to BPAP, CPAP, or no device) was associated with fewer hospital admissions (low SOE).

In patients with thoracic restrictive diseases (7 studies), common criteria for NIPPV initiation were PaCO2>45mmHg, and FVC<40% normal or MIP<60cmH2O, or nocturnal SaO2<88% for ≥ 5 consecutive minutes. HMV (compared with no device) was associated with lower mortality (low SOE).

In patients with neuromuscular disease (13 studies), common criteria for NIPPV initiation were PaCO2>45mmHg or FVC<50% or MIP<60cmH2O, or nocturnal SaO2<88% for ≥ 5 consecutive minutes. BPAP (compared with no device) was associated with reduced mortality (low SOE), and better quality of life (low SOE).

Evidence was insufficient to compare initiation criteria or determine the effect of specific home respiratory services on outcomes. Approximately one third of patients who use NIPPV via any device experienced non-serious adverse events such as facial rash, mucosal dryness, mask discomfort, etc. Based on direct comparisons, we found no significant differences in adverse events between devices or between devices and no device.

Home ventilator, multi-function respiratory device: In a January 11, 2019 Search and Summary report on VOCSN Unified Respiratory System (Ventec Life Systems Inc.), Hayes concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for the VOCSN Unified Respiratory System for patients requiring ventilator support. The use of the Ventilation, Oxygen, Cough, Suction, Nebulization (VOCSN) multifunction ventilator is considered not medically necessary as these functions can be provided by existing separate equipment. There is no comparative literature demonstrating that
the use of this multifunction device is more effective or leads to improved health outcomes than using separate pieces of equipment.

Professional Societies/Organizations

American Association for Respiratory Care (AARC): The AARC Clinical Practice Guideline Long-term Invasive Mechanical Ventilation in the Home (2007) refers to patients ventilated by positive pressure via a tracheostomy tube in the home. Patients requiring invasive long-term ventilator support have demonstrated:

- an inability to be completely weaned from invasive ventilatory support, or
- a progression of disease etiology that requires increasing ventilatory support.

Conditions that met these criteria may include but are not limited to ventilatory muscle disorders, alveolar hypoventilation syndrome, primary respiratory disorders, obstructive lung diseases, restrictive lung diseases, and cardiac disorders, including congenital anomalies.

Contraindications to invasive long term mechanical ventilation in the home include:

- the presence of a physiologically unstable medical condition requiring higher level of care or resources than available in the home
- patient's choice not to receive home mechanical ventilation
- lack of an appropriate discharge plan
- unsafe physical environment as determined by the patient’s discharge planning team
- inadequate resources for care in the home

American Thoracic Society (ATS) Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome: The ATS Clinical Practice Guideline Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome (Fan, et al., 2016) is an evidence-based clinical practice guideline on the use of ventilatory strategies and associated cointerventions in adult patients with acute respiratory distress syndrome (ARDS), providing treatment recommendations on the basis of these interventions. It does NOT specifically address home setting or portable ventilation.

1. The recommendations for the following interventions for the treatment of ARDS are strong:
   a. Mechanical ventilation using lower tidal volumes (4–8 ml/kg predicted body weight) and lower inspiratory pressures (plateau pressure,30 cm H2O) (moderate confidence in effect estimates)
   b. Prone positioning for more than 12 h/d in severe ARDS (moderate confidence in effect estimates)

2. The recommendation against the following intervention for the treatment of ARDS is strong:
   a. Routine use of high-frequency oscillatory ventilation in patients with moderate or severe ARDS (high confidence in effect estimates)

3. The recommendation for the following interventions for the treatment of ARDS is conditional:
   a. Higher positive end-expiratory pressure in patients with moderate or severe ARDS (moderate confidence in effect estimates)
   b. Recruitment maneuvers in patients with moderate or severe ARDS (low confidence in effect estimates)

4. Additional evidence is necessary to make a definitive recommendation for or against the use of extracorporeal membrane oxygenation in patients with severe ARDS.

American Thoracic Society (ATS) Pediatric Chronic Home Invasive Ventilation: The ATS Clinical Practice Guideline Pediatric Chronic Home Invasive Ventilation (Sterni, et al., 2016) is an evidence-based clinical practice guideline for health care professionals for the safe hospital discharge and home/community management of children requiring chronic invasive ventilation. The recommendations presented are based on the current
evidence and expert opinion and will require an update as new evidence and/or technologies become available. Recommendations regarding home equipment include:

- The ATS suggest the following pieces of equipment for use in the home when caring for a patient on home mechanical ventilation: the ventilator, a back-up ventilator, batteries, a self-inflating bag and mask, suctioning equipment (portable), heated humidifier, supplemental oxygen for emergency use, nebulizer, and a pulse oximeter (nonrecording) (Strength of Recommendation: Conditional; Quality of Evidence: Very Low).
- The ATS suggest that a mechanical insufflation–exsufflation (MI-E) device be used to help maintain airway patency in patients requiring home mechanical ventilation with ineffective cough, including, but not limited to, those with neuromuscular disease with poor respiratory muscle strength (Strength of Recommendation: Conditional; Quality of Evidence: Very Low).
- For children requiring chronic home invasive ventilation, the ATS suggest monitoring, especially when the child is asleep or unobserved, with a pulse oximeter rather than use of a cardiorespiratory monitor or sole use of the ventilator alarms (Strength of Recommendation: Conditional; Quality of Evidence: Very Low).
- For children requiring chronic home invasive ventilation, The ATS recommend regular maintenance of home ventilators and all associated equipment as outlined by the manufacturer.

**American Thoracic Society (ATS) Management of COPD Exacerbations:** The ERS/ATS Clinical Practice Guideline on the Management of COPD Exacerbations (Wedzicha 2017) notes the following:

- Should NIV be used in patients who are hospitalized with a COPD exacerbation associated with acute or acute-on-chronic respiratory failure? For hospitalized patients with acute or acute-on-chronic hypercapnic respiratory failure due to a COPD exacerbation, we recommend the use of NIV (strong recommendation, low quality of evidence).
- Should a home-based management programme (hospital-at-home) be implemented in patients with COPD exacerbations? For patients with a COPD exacerbation who present to the emergency department or hospital, we suggest a home-based management programme (hospital-at-home; conditional recommendation, moderate quality of evidence).

**American Thoracic Society (ATS) and European Respiratory Society (ERS) Clinical Practice Guideline Noninvasive Ventilation for Acute Respiratory Failure:** The ATS/ERS guideline does NOT specifically address home setting or portable ventilation (Rochwerg 2017). It makes recommendations regarding the current use of NIV for various forms of respiratory failure encountered in acute care settings.

**American Academy of Neurology (AAN) Practice Parameter Update on the care of the patient with Amyotrophic Lateral Sclerosis:** The AAN Care of the Patient with Amyotrophic Lateral Sclerosis: Drug, Nutritional, and Respiratory Therapies (Miller, et al., 2009; Reaffirmed on April 25, 2017) provides these:

Recommendations under Respiratory Management
- Nocturnal oximetry may be considered to detect hypoventilation (regardless of the forced vital capacity, FVC) (Level C*).
- Supine FVC and maximal inspiratory pressure (MIP) may be considered useful in routine respiratory monitoring, in addition to the erect FVC (Level C).
- Sniff nasal pressure (SNP) may be considered to detect hypercapnia and nocturnal hypoxemia (Level C).
- Noninvasive ventilation (NIV) may be considered to enhance quality of life (QOL) in patients with ALS who have respiratory insufficiency (Level C).
- Tracheostomy invasive ventilation (TIV) may be considered to preserve QOL in patients with ALS who want long-term ventilator support (Level C).
- NIV may be considered at the earliest sign of nocturnal hypoventilation or respiratory insufficiency in order to improve compliance with NIV in patients with ALS (Level C).
• Mechanical insufflation/exsufflation (MIE) may be considered to clear secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection (Level C).
• There are insufficient data to support or refute high frequency chest wall oscillation (HFCWO) for clearing airway secretions in patients with ALS (Level U).

Recommendations for Future Research: Respiratory management:
1. Evaluate SNP as a criterion for NIV initiation.
2. Evaluate the impact of early NIV initiation on survival and quality of life.
3. Assess the impact of executive dysfunction on NIV compliance.
4. Evaluate the effect of hypoventilation on executive dysfunction.
5. Compare techniques for clearing upper airway secretions at various stages of respiratory and bulbar dysfunction.
6. Evaluate pulmonary tests, compliance with NIV, and outcomes in patients with bulbar dysfunction.

* C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)
U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

American Academy of Neurology (AAN) Consensus-based care recommendations for adults with myotonic dystrophy type 1: The AAN care recommendations (Ashizawa, et al 2018) note the following:

- Under section Life threatening symptoms—Clinical care recommendations
  - Vaccinate for pneumonia and flu; treat respiratory infections quickly and use cough assistance and mechanical ventilation as needed along with obtaining consultations from respiratory therapy and pulmonary medicine groups.
  - Some patients will eventually require either nighttime ventilator support or full-time ventilation. Most patients with chronic respiratory insufficiency respond to noninvasive ventilatory support (NIV). Patients experiencing acute respiratory failure require endotracheal intubation with positive pressure ventilation.
  - For chronic respiratory insufficiency, use supplemental oxygen with caution and in conjunction with NIV (see Surgery, anesthesia, and pain).
  - If surgery is planned, reassess clearance capacity if needed, possible adaptation to NIV or cough assistance.

- Under section re Excessive daytime sleepiness (EDS) symptoms:
  - If nocturnal or daytime hypoventilation is suspected, consider noninvasive positive pressure ventilation, and refer to a pulmonologist with experience in neuromuscular diseases re: possible need for NIV launching.

- Under Pregnancy / Obstetrical management:
  - Include a pediatric or neonatal specialist present at delivery; intensive neonatal care is recommended for neonates that may have DM1; anticipate need for feeding tube and ventilator support (recommended even if the fetus is known to be unaffected).

The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative
No specific relevant information.

Centers for Medicare & Medicaid Services (CMS)
- National Coverage Determinations (NCDs): The NCD for Durable Medical Equipment Reference List (280.1) addresses Ventilators: Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive and negative pressure types (Implementation Date 7/5/2005).
- Local Coverage Determinations (LCDs): None
Use Outside of the US
The German National Guideline for Treating Chronic Respiratory Failure with Invasive and Non-Invasive Ventilation (Windisch, et al., 2018) notes that invasive and non-invasive home mechanical ventilation have become a well-established treatment option. Consequently, new chapters have been added to the guideline.

Non-Invasive Ventilation Recommendations
- Home access to non-invasive ventilation must be granted after considering the technical advantages and disadvantages, the individual patient tolerance levels, and the results of clinical testing.
- Commercial masks are usually sufficient. Customized masks must only be used under exceptional circumstances such as in neuromuscular disease patients, with high ventilation pressures or long ventilation times, or in patients with sensitive skin.
- Every patient should have a spare mask.
- Hybrid or special ventilation modes such as mandatory target volume cannot be recommended on a general basis.
- A second ventilation machine and an external battery are necessary for ventilation times ≥16 h/24 h.

Invasive Ventilation Recommendations
- The tracheostoma should be surgically created; proof of stability is absolutely necessary for percutaneous dilational tracheostomata.
- A second ventilation machine and an external battery are essential for ventilation times ≥16 h/24 h.
- A pulse oximeter is necessary for selective measurements and possibly for continuous measurements in certain disease groups (i.e., spinal cord transection, paediatrics).
- A small-diameter spare cannula must be made available.
- For application of speaking valves, a cuffless cannula, a completely unblocked cannula, or a fenestrated cannula must be used.
- Conditioning (humidification and moistening) of the ventilation air is mandatory.
- Two aspirator devices are necessary.

Obstructive Airway disease Recommendations
- Non-invasive ventilation is the primary therapeutic option for home mechanical ventilation of chronic obstructive pulmonary disease patients with chronic respiratory failure.
- Home non-invasive ventilation must be initiated when the patient presents with chronic hypercapnia in combination with the typical symptoms of respiratory failure.
- Home non-invasive ventilation must be initiated when hypercapnia persists for more than 2 weeks after completing acute ventilation therapy for acute respiratory acidosis.
- The aim of the ventilation therapy is to normalise PaCO2; this may require sufficiently high ventilation intensity with effective ventilation pressures as well as the use of controlled ventilation modes.

Thoracic-Restrictive Lung Diseases Recommendations
- Non-invasive ventilation is the primary therapeutic option for home mechanical ventilation of thoracic-restrictive disease patients with chronic respiratory failure. The most important criteria for beginning long-term non-invasive ventilation are hypercapnia in combination with both the typical symptoms of chronic respiratory failure and the reduction in quality of life.
- For symptoms of hypoventilation in the absence of hypercapnia, a sleep study should take place.
- Patients with severe restrictive ventilatory dysfunction but without manifest hypercapnia must be closely monitored.

Obesity Hypoventilation Syndrome Recommendations
- Continuous positive airway pressure or non-invasive ventilation are the primary treatment options for home mechanical ventilation in patients with obesity hypoventilation syndrome.
- A primary attempt at continuous positive airway pressure therapy must take place under poly (somno)graphic evaluation. Primary non-invasive ventilation can be indicated in the presence of significant comorbidities or severe hypercapnia.
• A switch to non-invasive ventilation is indicated in the following cases: continuous positive airway pressure intolerance, persistent sleep-related or aggravated hypoventilation, and/or persistent sleep-related respiratory dysfunction despite continuous positive airway pressure use.
• Concomitant weight loss should be aimed for.
• A therapeutic switch from non-invasive ventilation to continuous positive airway pressure should be considered under stable conditions, particularly after weight reduction; if applicable, omission of mechanical ventilation can be considered.
• If obesity hypoventilation syndrome is clinically suspected, appropriate diagnostic tests for obesity hypoventilation syndrome should take place before undergoing general anaesthetics.

Neuromuscular Diseases Recommendations
• Clinical assessment and determination of forced vital capacity in neuromuscular disease patients should take place at 3- to 12-month intervals. A forced vital capacity < 70% is an indicator for poly(somno)graphy and PtcCO2 measurement.
• In the event of mild hypercapnia (PaCO2 ≥ 45 mm Hg or diurnal normocapnia with a nocturnal rise in PtcCO2 of ≥ 10 mm Hg), non-invasive ventilation should be implemented as the primary therapy option for home mechanical ventilation in neuromuscular disease patients with chronic respiratory failure, if diurnal symptoms persist.
• There is no indication for prophylactic implementation of non-invasive ventilation in the absence of chronic respiratory failure.
• The measurement of coughing capacity is obligatory in neuromuscular disease patients. The presence of weak cough (peak cough flow < 270 L/min) is an indication for the introduction of secretion management.

Secretion Management Recommendations
• In neuromuscular disease patients with impaired cough and invasive ventilation, secretion management is obligatory and must be carried out regularly and adapted to the underlying disease.
• The indication for a mechanical In-Exsufflator device must be established by a physician with ventilation competency, who also then takes over the responsibility for the patient’s therapy.
• Adaptation of the mechanical In-Exsufflator to the patient can be performed by a respiratory therapist.
• Switching between different types of mechanical In-Exsufflators that are not structurally identical may not be carried out without renewed testing of the effectiveness and patient compatibility of the devices; this is because the performance of each device may differ significantly.
• Secretion management in chronic obstructive pulmonary disease patients with high secretion load must include measures for secretolysis (medicinal/non-medicinal) and measures to ease coughing such as special coughing techniques (huffing) and positive expiratory pressure systems.
• Mechanical In-Exsufflators should not be used in chronic obstructive pulmonary disease patients.
• Suctioning in invasively ventilated patients must take place strictly via endotracheal placement of the suctioning catheter (max. 1 cm beyond the cannula), independent of the underlying condition.

Spinal Cord Transection Recommendations
• Permanent pulse oximetry monitoring is necessary in partly and fully dependent mechanically ventilated patients with spinal cord transection.
• Capnographic monitoring of patients with spinal cord transection injuries is indicated in many situations in the home mechanical ventilation setting.

Special Features of Pediatric Ventilation
• Due to their difference from adults, the care and ventilation of children with chronic respiratory failure must be carried out by a multidisciplinary team.
• Safe and successful home mechanical ventilation therapy must take into account the family and home environment of the patient and be accompanied by offers of medical, nursing, and psychosocial support.
• Continuous monitoring of oxygen saturation (at the least), and PCO2 (if necessary) must be carried out in children who are dependent on mechanical ventilation for survival.
• The development of paediatric competence centres that initiate home mechanical ventilation should be aimed at for better care of long-term-ventilated children (Windisch, et al., 2018).
The Canadian Thoracic Society Clinical Practice Guideline on Home Mechanical Ventilation (McKim, et al, 2011) notes that guideline applies to all adult individuals who are at risk for or are using HMV. Individuals with amyotrophic lateral sclerosis (ALS), central hypoventilation syndrome (CHS), chronic obstructive pulmonary disease (COPD), kyphoscoliosis, obesity hypoventilation syndrome (OHS), spinal cord injury (SCI), Duchenne muscular dystrophy (DMD), muscular dystrophies (MDs) other than DMD, myopathies and myotonic dystrophy (Steinert’s muscular dystrophy [SMD]) are of special interest and are considered individually in the present clinical practice guideline.

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0465</td>
<td>Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube)</td>
</tr>
<tr>
<td>E0466</td>
<td>Home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell)</td>
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</tbody>
</table>

Considered Not Medically Necessary:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0467</td>
<td>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</td>
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</table>


**References**


12. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=190&amp;amp%3Bamp%3Bncdver=2&amp;amp%3Bamp%3BNCAId=3&amp;amp%3Bamp%3Bver=5&amp;amp%3Bamp%3BNcaName=Air-Fluidized%2BBeds%2Bfor%2BPressure%2BUlcers&amp;amp%3Bamp%3Bbbc=ACAAAAAAIAAA


