When should a ventilator or respiratory assist device (RAD) be considered?

Items may only be covered based upon the reasonable and necessary (R&N) criteria applicable to the product. The Centers for Medicare & Medicaid Services (CMS) National Coverage Determination Manual (Internet-Only Manual, Publ. 100-3) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators are covered for the following conditions:

- Neuromuscular diseases, thoracic restrictive diseases and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

These ventilator-related disease groups overlap conditions described in the Respiratory Assist Devices LCD used to determine coverage for bilevel PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bilevel PAP device, is made based upon the specifics of each individual beneficiary’s medical condition. In the event of a claim review, there must be sufficiently detailed information in the medical record to support the treatment selected.

Billing criteria for ventilators

Ventilators are covered by Medicare for the treatment of neuromuscular diseases, thoracic restrictive diseases and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

Ventilators are included in Medicare’s Frequent and Substantial Servicing (FSS) payment category. Equipment in this payment category is paid on a monthly rental basis while the equipment is medically necessary. The monthly rental payment for items in this payment category is all-inclusive, meaning there is no separate payment by Medicare for any options, accessories or supplies used with a ventilator. In addition, all necessary maintenance, servicing, repairs and replacement are also included in the monthly rental.

In order to justify payment for a ventilator, suppliers must meet the following:

- Standard Written Order (SWO) that includes:
  - Beneficiary’s name or Medicare Beneficiary Identifier (MBI)
  - Order date
  - General description of the item
    - The description can be either a general description (e.g. wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - For equipment: In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately).
  - Treating practitioner name or NPI and signature
- Correct coding
- Medical Record Information, including continued need/use if applicable (see Q&A)
- Proof of delivery

### Reimbursement fast facts: ventilators

#### Understanding Medicare coding and coverage

**Ventilators** are medical devices that provide mechanical ventilation to assist with or replace patients’ spontaneous breathing. Mechanical ventilation is often categorized by the interface used, such as a tracheostomy tube for invasive ventilation, or a mask for non-invasive ventilation.

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
<th>HCPCS code</th>
<th>Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home ventilator: Invasive</td>
<td>Home ventilator, any type, used with invasive interface (e.g. tracheostomy tube)</td>
<td>E0465</td>
<td></td>
</tr>
<tr>
<td>Home ventilator: Non-invasive</td>
<td>Home ventilator, any type, used with non-invasive interface (e.g. mask, chest shell)</td>
<td>E0466</td>
<td>[Fee Schedule Lookup Tool]</td>
</tr>
</tbody>
</table>

**Billing criteria for ventilators**

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  - Order date
  - General description of the item
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- Correct coding
- Medical Record Information, including continued need/use if applicable (see Q&A)
- Proof of delivery
Q & A

Q: What additional items are typically supplied to ventilation patients?
Since ventilators are covered under the FSS payment category, bills for supplies and accessories are not separately covered. However, other items may be medically necessary. Depending on the patient’s condition, items like oxygen, nebulizers, suction machines and tracheostomy supplies may also be provided. Please check with Medicare to confirm coverage and billing details for other items.

Q: Are humidifiers separately reimbursable?
No, under the FSS payment category, humidifiers are bundled into the ventilator reimbursement and are not separately covered. When a ventilator is purchased by the beneficiary or acquired before Medicare eligibility, separate reimbursement may be considered. Verify coverage with Medicare prior to billing.

Q: Is a face-to-face meeting required prior to writing an SWO for a ventilator?
No. At the time of this writing, the face-to-face encounter and written order prior to delivery (WOPD) are not statutorily required. CMS and the DME MACs will post on their websites the “Required List” of the selected HCPCS codes subject to face-to-face and WOPD, once published through the Federal Register Notice.¹

Q: Can a supplier bill for a positive airway pressure (PAP) device in addition to a ventilator?
Items may only be covered based upon the reasonable and necessary (R&N) criteria applicable to the product. A PAP or bilevel device (E0601, E0470, E0471) cannot be covered simultaneously. If the primary diagnosis is OSA, ventilator coverage will be denied as not reasonable and necessary.

Q: Can a supplier bill for a second ventilator or a backup ventilator?
Medicare does not cover spare or back-up equipment but will make a separate payment for a second piece of equipment if it is required to serve a different medical purpose that is determined by the beneficiary’s medical needs.¹

Examples of situations in which multiple items may be covered (not all-inclusive):

- A beneficiary requires one type of ventilator (e.g. a negative pressure ventilator with a chest shell) for part of the day and needs a different type of ventilator (e.g. positive pressure ventilator with a nasal mask) during the rest of the day.
- A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day, and needs another ventilator of the same type for use while in bed. Without two pieces of equipment, the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively.

Q: What documentation can be used to prove continued medical need?
Any of the following may serve as documentation justifying continued medical need:

- A recent order/prescription by the treating practitioner for refills
- A recent change in an order/prescription
- A properly completed Certificate of Medical Necessity (CMN) or DME Information Form (DIF) with an appropriate length of need specified
- Timely documentation in the beneficiary’s medical record showing usage of the item
  “Timely documentation” is defined as a record in the preceding twelve (12) months unless otherwise specified elsewhere in the policy.

Q: Does Medicare cover repairs or maintenance for ventilators?
Ventilators fall into the FSS payment category, and neither repairs nor maintenance and servicing are covered during rental period. Check with Medicare for payment of beneficiary-owned equipment.

For more information on RADs, please reference:
- ResMed RAD Guidelines, PN 1010293
- CMS’ RAD LCD (L33800) effective date 10/1/2015