

State of Vermont
Department of Vermont Health Access
280 State Drive, NOB 1 South
Waterbury, VT 05671-1010
www.dvha.vermont.gov

Agency of Human Services [Phone] 802-879-5903 [Fax] 802-879-5963

The Department of Vermont Health Access Clinical Criteria

Subject: Home Mechanical Ventilation

Last Review: June 27, 2023*

Past Revisions: March 26, 2021, September 25, 2019, April 4, 2017, April 25, 2016, February 20, 2015,

June 11, 2013, September 14, 2011, 2004

*Please note: Most current content changes will be highlighted in yellow.

Description of Service or Procedure

A ventilator is a device which moves air in and out of the lungs for an individual who requires mechanical assistance to breathe.

- Invasive ventilation: ventilator generated breathing through an artificial airway positioned in the trachea.
- Noninvasive ventilation: ventilator generated breathing through the upper respiratory tract via mask or mouthpiece.
- Negative pressure ventilator: noninvasive device which moves air in and out of the lungs by
 creating negative pressure around the chest. This creates a vacuum, via a chest shell, body tank, or
 body jacket.
- Positive pressure ventilator: invasive or noninvasive device that delivers positive pressure gas flow (air or oxygen) to the lungs to a preset volume. Some individuals who can be ventilator-independent for part of the day may use positive pressure ventilation to assist nighttime breathing.
- Indications for invasive and non-invasive positive pressure ventilation using a home ventilator include but are not limited to:
 - Members with diagnosis of COPD with chronic severe hypercapnia stable state or following recovery.
 - Thoracic restrictive disease neuromuscular disease, ALS, Spinal Muscular Atrophies and muscular dystrophies, fibrotic lung disease, and kyphoscoliois
 - Spinal cord injury
 - Obesity related respiratory failure
 - Other respiratory diseases diffuse parenchymal lung disease and/or bronchiectasis, hypoxia and or hypercapnia
 - Chronic ventilatory insufficiency
 - Non-invasive failure of bilevel positive airway pressure to improve hypercapnia and/or oxygen saturation level



Coverage of Ventilator Accessories: Effective for dates of service on or after May 1, 2018, providers may bill for supplies up to the DVHA quantity limit during the rental period for: E0445, E0465, E0466, E0470, E0471, E0565, E0600, and E0601. See the Vermont Medicaid Provider Manual, <u>Durable Medical Equipment Supplement</u>, section 2.2. All provider manuals can be found at: http://vtmedicaid.com/#/manuals.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2	Prior Authorization Determination
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered Services
4.209	Durable Medical Equipment
4.106	Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

A ventilator and accessories for home use may be covered for member's:

- When a ventilator and accessories are prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, who is knowledgeable in the use of ventilators and who provides medical care to the member, AND
- When the clinical criteria below are met.

Coverage Criteria

This is a rented item only and the vendor/manufacturer maintains sole responsibility for the proper function and maintenance of the equipment.

This device may be covered for members who require mechanical assist to breathe, and:

- Have had a full evaluation to determine the need for a ventilator and the most appropriate type of ventilator, with a physician who is skilled in respiratory assisted ventilation and/or pulmonology medicine
- Have been evaluated for strategies to minimize ventilator use (weaning or partial weaning from the ventilator) including breathing techniques and diaphragmatic pacer devices



^{*} Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

- Have a comprehensive discharge plan in place that includes person-centered care for member and family to optimized quality of life,
- Integrated Care structure to include transition coordination and collaboration is in place to ensure quality of care service delivery
- Routine case conferences should be routinely held with an assignment of a point person for member and family.
- Agencies providing staff to care for members on a home ventilator must have policies procedures in place.
- Staff must be adequately trained with documentation of performance and skill competencies prior to providing care
- Agency caregivers should be provided with educational opportunities to remain abreast of current practice and technology.
- Family members must be adequately trained, with documentation of competency of the skills as determined by a return demonstration, prior to caring for the member in the home. Including how to change filters and review alarm settings and their functions.
- American Thoracic Society (ATS) that at least two specifically trained family caregivers be in the home at all times for children on invasive ventilation.
- Battery back-up and a ventilator circuit must be provided by the vendor.
- Alarms and ventilator settings should be monitored to ensure member safety.
- Family/member should have access to a trained professional in respiratory care and ventilator management for technical and clinical support 24 hours a day.
- Regular maintenance of home ventilators and all associated equipment is completed as outlined by the manufacturer.
- Care should be taken to assure that the actual ventilator settings as seen on the control panel match the prescribed settings.
- DME respiratory clinicians should visit patients at least monthly or per company policy.

In alignment with Medicare, Vermont Medicaid does not cover backup equipment. Claims for backup equipment will be denied for lack of medical necessity (Medicaid HCAR Rule 4.101). From CMS, backup equipment must be distinguished from multiple medically necessary items which are defined as, identical or similar devices each of which meets a different medical need for the member. Medicaid will make a separate payment for a second piece of equipment if it is determined to be medically necessary AND will serve a separate medical purpose that is determined by the member's medical needs. The following are examples of situations in which a member would qualify for both a primary ventilator and a secondary ventilator:

- A member 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 member 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 member may be prone to certain medical complications, may be unable to achieve certain appropriate medical outcomes, or may be unable to use the medical equipment effectively.



- Prior Authorization is required for the secondary ventilator.
- An additional or duplicate home ventilator device (HCPCS E0465-E0466) is considered NOT medically necessary as a backup device (similar device as the individual's primary ventilator, for multiple residences or to have in case of possible malfunction) except under extenuating circumstances.

Please note: In accordance with Medicare, it is expected that the DME supplier have an acceptable contingency plan in place to address emergency situations or equipment failure that would be life threatening. This plan should involve input from the treating physician and would take into account the severity of the member's condition and proximity for access to services, including emergency services. The member's Durable Medical Equipment (DME) provider is responsible for ensuring that the member's medical needs will be met on a continuous and ongoing basis.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Repeat service is limited to the guidelines above.

Type of service or procedure covered

Ventilator and related supplies and services. Mechanical ventilators are always rented. Providers may bill for supplies up to the DVHA quantity limit during the rental period for certain supplies. Please refer to the DME Provider Manual Section 2.2 Rental/Loaned found at http://vtmedicaid.com/assets/manuals/DMESupplement.pdf for the list of supplies that may be billed up to the DVHA quantity limit during a rental period.

Type of service or procedure not covered (this list may not be all inclusive)

Multi-Function/Multi-Use Ventilators (VOCSN) (E0467): is a noncovered Medicaid item.

A home ventilator device (HCPCS E0465-E046) is considered NOT medically necessary for any of the following:

- A non-life-threatening condition
- When the sole purpose of the home ventilator is to function 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)



- Treatment for obstructive sleep apnea
- Member's choice not to receive home mechanical ventilation.
- Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements

References

- American Association for Respiratory Care. (2007). Long-Term Invasive Mechanical Ventilation in the Home 2007 Revision & Update. *Respiratory Care*, 52(8), 1056–1062. https://rc.rcjournal.com/content/52/8/1056/tab-article-info
- American Association for Respiratory Care, & University Health System Consortium's Respiratory Care Network. (2016). Safe Initiation and Management Of Mechanical Ventilation.

 https://www.aarc.org/wp-content/uploads/2016/05/White-Paper-SAFE-INITIATION-AND-MANAGEMENT-OF-MECHANICAL-VENTILATION.pdf
- Brandt, H., Simon, D. M., & Kasi, A. S. (2021). Ventilator change in children on home mechanical ventilation affected by the Philips Respironics Trilogy ventilator recall. *Pediatric Pulmonology*, 57(1), 43–48. https://doi.org/10.1002/ppul.25730
- Centers for Medicare and Medicaid Services. (2022, December). *DMEPOS Quality Standards ICN MLN905709*. Www.cms.gov. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html
- Centers for Medicare and Medicaid Services. (2017). *Early and Periodic Screening, Diagnostic, and Treatment* | *Medicaid.gov*. Medicaid.gov; Centers for Medicare and Medicaid Services. https://www.medicaid.gov/medicaid/benefits/epsdt/index.html
- Kim, E. Y., Suh, H. J., Seo, G., Jang, M. K., Lim, C.-M., & Huh, J. W. (2023). Predictors of early hospital readmission in patients receiving home mechanical ventilation. *Heart & Lung*, *57*, 222–228. https://doi.org/10.1016/j.hrtlng.2022.10.004
- Klingshirn, H., Gerken, L., Hofmann, K., Heuschmann, P. U., Haas, K., Schutzmeier, M., Brandstetter, L., Ahnert, J., Wurmb, T., Kippnich, M., & Reuschenbach, B. (2021). How to improve the quality of care for people on home mechanical ventilation from the perspective of healthcare professionals: a qualitative study. *BMC Health Services Research*, 21(1). https://doi.org/10.1186/s12913-021-06743-3
- Marcus, E. L., Jacobs, J. M., & Stessman, J. (2022). Prolonged mechanical ventilation and caregiver strain: Home vs. long-term care facility. *Palliative and Supportive Care*, 1–9. https://doi.org/10.1017/s147895152200027x
- Park, S., & Suh, E.-S. (2020). Home mechanical ventilation: Back to basics. *Acute and Critical Care*, 35(3), 131–141. https://doi.org/10.4266/acc.2020.00514
- Potchileev, I., Doroshenko, M., & Mohammed, A. N. (2021). *Positive Pressure Ventilation*. NIH National Library of Medicine; StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK560916/
- Restrepo, R. D., & Walsh, B. K. (2012). Humidification during invasive and noninvasive mechanical ventilation. *Respiratory Care*, *57*(5), 782–788. https://doi.org/10.4187/respcare.01766



- Ribeiro, C., Jácome, C., Oliveira, P., Conde, S., Windisch, W., & Nunes, R. (2022). Patients experience regarding home mechanical ventilation in an outpatient setting. *Chronic Respiratory Disease*, 19. https://doi.org/10.1177/14799731221137082
- Sison, S. M., Sivakumar, G. K., Caufield-Noll, C., Greenough, W. B., Oh, E. S., & Galiatsatos, P. (2021). Mortality outcomes of patients on chronic mechanical ventilation in different care settings: A systematic review. *Heliyon*, 7(2), e06230. https://doi.org/10.1016/j.heliyon.2021.e06230
- U.S. Department of Health and Human Services. (2016). *Escalating Medicare Billing for Ventilators Raises Concerns*. https://oig.hhs.gov/oei/reports/oei-12-15-00370.pdf
- Viegas, P., Ageno, E., Corsi, G., Tagariello, F., Razakamanantsoa, L., Vilde, R., Ribeiro, C., Heunks, L., Patout, M., & Fisser, C. (2021). Highlights from the Respiratory Failure and Mechanical Ventilation 2022 Conference. *ERJ Open Research*, *9*(2), 00467-2022. https://doi.org/10.1183/23120541.00467-2022
- Wilson, M., Wang, Z., Dobler, C., Morrow, A., Beuschel, B., Alsawas, M., Benkhadra, R., Seisa, M., Mittal, A., Sanchez, M., Daraz, L., Holets, S., & Murad, M. H. (2020). *Noninvasive Positive Pressure Ventilation in the Home Technology Assessment Program*. https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id108TA.pdf

