



MEDICAL POLICY STATEMENT

Ohio Medicaid

| Policy Name & Number | Date Effective |
|---|----------------|
| Airway Clearance Devices-OH MCD-MM-1578 | 07/01/2026 |
| Policy Type | |
| MEDICAL | |

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

| | |
|----------------------------------|---|
| A. Subject | 2 |
| B. Background | 2 |
| C. Definitions | 2 |
| D. Policy | 2 |
| E. Conditions of Coverage | 4 |
| F. Related Policies/Rules | 4 |
| G. Review/Revision History | 4 |
| H. References | 4 |

A. Subject

Airway Clearance Devices

B. Background

Healthy individuals typically produce 10 –100 mL of airway secretions daily. The clearance of these secretions from the respiratory tract is accomplished primarily through ciliary action, called the mucociliary escalator and the cough reflex.

Secretion retention can occur because of an increased production of secretions due to a number of conditions, including asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), mucociliary disorders, neuromuscular disease (NMD), and metabolic disorders that make it more difficult to clear the airway. In patients with a weak cough, retention of these secretions is a major cause of mortality and morbidity.

Conventional chest physical therapy has been shown to result in improved respiratory function through the use of percussion and postural drainage. These techniques are usually taught to family members so therapy may be continued at home when needed for chronic disease. However, this highly labor-intensive activity requires the daily intervention of a trained caregiver and may lead to poor compliance with the recommended treatment plan.

Airway clearance devices can aid secretion mobilization and expectoration and assist coughing. Educating patients and families on the use of these devices and secretion management are within the scope of practice of respiratory therapists, physical therapists, nurses, and other clinicians.

C. Definitions

- **High Frequency Chest Compression Device** – An inflatable vest connected by tubes to a small air-pulse generator. The air-pulse generator rapidly inflates and deflates the vest, compressing and releasing the chest wall up to 20 times per second.
- **Mechanical Insufflation-Exsufflation Device** – A device with a facemask that covers the nose and mouth, allowing air to be pumped into the lungs and then rapidly evacuated, facilitating the expulsion of secretions.
- **Oscillation and Lung Expansion (OLE) Device** – A non-invasive, mechanical airway clearance technique (ACT) that combines continuous high-frequency oscillation (CHFO) and continuous positive expiratory pressure (CPEP) to treat lung diseases.

D. Policy

I. Mechanical Insufflation-Exsufflation Devices (E0482)

- A. CareSource considers mechanical in-exsufflation devices medically necessary when **all** of the following clinical criteria are met:

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

1. There is a presence of neuromuscular or chest wall disease (eg, amyotrophic lateral sclerosis, congenital muscular dystrophies, Duchenne muscular dystrophy, multiple sclerosis, post-poliomyelitis, spinal cord injury, spinal muscle atrophy).
 2. The condition causes a significant impairment of chest wall and/or diaphragmatic movement, resulting in an inability to clear retained secretions.
 3. The member has an inadequate response or intolerance to chest percussion and postural drainage.
 4. Member has no bullous emphysema, pneumomediastinum, or pneumothorax.
- B. A mechanical insufflation-exsufflation device for any indication not listed above is not covered or reimbursable.
- II. High Frequency Chest Compression Devices (E0483)
- A. CareSource considers high frequency chest compression devices medically necessary when **any** of the following clinical criteria is met:
1. cystic fibrosis when there is failure, intolerance or contraindication to home chest physiotherapy, or it cannot be provided
 2. a diagnosis of bronchiectasis which has been confirmed by a high resolution, spiral, or standard CT scan and which is characterized by
 - a. daily productive cough for at least 6 continuous months or
 - b. frequent (eg, more than 2 per year) exacerbations requiring antibiotic therapy
- B. Chronic bronchitis and chronic obstructive pulmonary disease (COPD) in the absence of a confirmed diagnosis of bronchiectasis do not meet this criterion.
- C. It is not reasonable and necessary for a member to use **both** a high frequency chest compression device and a mechanical in-exsufflation device.
- D. Per Ohio Administrative Code (OAC) 5160-10-08, purchase of a high-frequency chest wall oscillation (HFCWO) device will not be considered:
1. without an initial trial period lasting at least 2 months, excluding any portion that coincides with an inpatient hospital stay
 2. Payment for rental may be made during this trial period.
- E. If use of the HFCWO device is to be continued in a residential setting after the initial trial period, a Certificate of Medical Necessity (CMN) is included that contains
1. an attestation to the effectiveness of the device during the trial period and every previous rental period as exhibited by a decrease in (not all inclusive):
 - a. infections
 - b. hospitalizations and
 - c. antibiotic use
 2. if applicable, specification of a change in the duration or frequency of therapy
 3. a recommendation either for additional rental or for purchase
- III. Oscillation and Lung Expansion (OLE) Devices
- A. Combination oscillation and lung expansion (OLE) devices for the treatment of respiratory conditions (e.g., the Volara System, BiWaze Clear System, and

MetaNeb4 System) as an alternative to conventional chest physical therapy to promote the clearance of respiratory secretions are considered to be of unproven efficacy. OLE devices are not recommended for outpatient use due to insufficient evidence and safety concerns. Requests will be reviewed on a case-by-case basis.

- B. A review in Clintrials.gov of the Volara device revealed 1 completed pilot study of 20 participants completed on March 19, 2025. Another study of OLE therapy was terminated on Feb.27, 2024 and a third study as of 2025-04-22 is listed as Not Yet Recruiting.
- C. There is insufficient evidence in the peer-reviewed published medical literature to draw conclusions regarding improvements in health outcomes of these devices compared to established alternatives.

E. Conditions of Coverage

Based on 2 Class 1 FDA recalls (the most recent being on May 30, 2024) as well as a Hayes 2023 *Evidence Analysis Research Brief* which detailed the following adverse events: injuries, 5 malfunctions, 2 deaths, Volara is **not** recommended for outpatient use.

F. Related Policies/Rules

NA

G. Review/Revision History

| DATE | | ACTION |
|-----------------------|------------|---|
| Date Issued | 01/17/2024 | New policy. Approved at Committee. |
| Date Revised | 11/20/2024 | Updated references. Approved at Committee. |
| | 06/18/2025 | Updated references. Approved at Committee. |
| | 11/19/2025 | Added effectiveness criteria to D.II.E.1, removed D.II.F. Volara section, added section D.III.A-C OLE devices, updated references. Approved at Committee. |
| Date Effective | 07/01/2026 | |
| Date Archived | | |

H. References

1. Bach JR. Noninvasive respiratory management of patients with neuromuscular disease. *Ann Rehabil Med*. 2017;41(4):519-538. doi:10.5535/arm.2017.41.4.519
2. Basavaraj A, Choate R, Addrizzo-Harris D, et al. Airway clearance techniques in bronchiectasis: analysis from the United States Bronchiectasis and Non-TB Mycobacteria Research Registry. *Chest*. 2020;158(4):1376-1384. doi: 10.1016/j.chest.2020.06.050
3. Chatwin M, Wakeman RH. Mechanical insufflation-exsufflation: considerations for improving clinical practice. *J Clin Med*. 2023;12(7):2626. doi:10.3390/jcm12072626

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

4. DMEPOS: High-Frequency Chest Wall Oscillation (HFCWO) Devices, OHIO ADMIN. CODE 5160-10-08 (2024).
5. Evidence Analysis Research Brief. Volara (Hillrom) for Respiratory Therapy. Updated August 2023. Accessed January 29, 2026. www.evidence.hayesinc.com
6. Ferreira de Camillis ML, Savi A, Goulart Rosa R, et al. Effects of mechanical insufflation-exsufflation on airway mucus clearance among mechanically ventilated ICU subjects. *Respir Care*. 2018;63(12):1471-1477. doi:10.4187/respcare.06253
7. Finder JD, Birnkrant D, Carl J, et al. Respiratory care of the patient with Duchenne muscular dystrophy: ATS consensus statement. *Am J Respir Crit Care Med*. 2004;170(4):456-465. doi:10.1164/rccm.200307-885ST
8. High Frequency Chest Compression Device: A-0356 (AC). MCG Health. 29th ed. 2024. Updated June 13, 2025. Accessed October 24, 2025. www.careweb.careguidelines.com
9. Main E, Rand S. Conventional chest physiotherapy compared to other airway clearance techniques for cystic fibrosis. *Cochrane Database Syst Rev*. 2023;5(5):CD002011. Published 2023 May 5. doi:10.1002/14651858.CD002011.pub3
10. Mechanical Insufflation-Exsufflation Device: A-0884 (AC). MCG Health. 29th ed. 2025. Updated June 13, 2025. Accessed October 24, 2025. www.careweb.careguidelines.com
11. Raywood E, Shannon H, Filipow N, et al. Quantity and quality of airway clearance in children and young people with cystic fibrosis. *J Cyst Fibros*. 2023;22(2):344-351. doi: 10.1016/j.jcf.2022.09.008
12. Strickland SL, Rubin BK, Drescher GS, et al. AARC clinical practice guideline: effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. *Respir Care*. 2013;58(12):2187-2193. doi:10.4187/respcare.02925

Approved by ODM on 3/20/2026