



MEDICAL POLICY STATEMENT

TrueCare

Policy Name & Number	Date Effective
Airway Clearance Devices-TrueCare-MM-1793	08/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements 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 or Certificate of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other plan policies and procedures.

Medical Policy Statements do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage or Certificate of Coverage) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract, then the plan contract 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.

D. Policy

- I. Per Mississippi Administrative code, these devices may not be appropriate for children less than 6 years of age.
 - A. For the item to be considered for children under age 6, the ordering physician or allowed NPP conducting the face-to-face encounter must document that the child is able to use the device correctly.
 - B. Individual case-by-case consideration will be given for children under age 6
- II. Mechanical Insufflation-Exsufflation Devices (E0482)
 - A. TrueCare 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.

III. High Frequency Chest Compression Devices (E0483)

- A. TrueCare 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. If use of the high-frequency chest wall oscillation (HFCWO) device is to be continued in a residential setting after the initial 2 month trial period, a Certificate of Medical Necessity (CMN) containing
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

IV. 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.
- 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.
- D. 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: 9 injuries, 5 malfunctions, 2 deaths, **Volara is not recommended for outpatient use.**

E. Conditions of Coverage
N/A

F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	06/18/2025	New policy. Approved at Committee.
Date Revised	12/03/2025	Added 2 month trial period to II.D and effectiveness criteria to II.D.1. Updated references. Approved at Committee.
	04/22/2026	Added Sec. III. Oscillation and Lung Expansion (OLE) Devices
Date Effective	08/01/2026	
Date Archived		

H. References

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DOM Approved - DOM060826.64