# MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|---|---|
| **Medical Policy Title** | **Airway Clearance Devices** |
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| **Category** | **Technology Assessment** |
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| **Product Disclaimer** | • *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*<br>• *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.*<br>• *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.*<br>• *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*<br>• *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.* |

## POLICY STATEMENT

I. Oscillatory Devices

A. Based upon our criteria and assessment of the peer-reviewed literature, the Flutter Valve, Lung Flute and Acapella device have been medically proven to be effective and, therefore, are considered **medically appropriate** for persons with hypersecretory lung disorders.

B. Based upon our criteria and assessment of the peer-reviewed literature, the Vibralung Acoustical Percussor is considered **medically appropriate** when **ALL** of the following criteria are met:

1. The patient has a documented disease, such as cystic fibrosis, ciliary dyskinesia, or bronchiectasis, that impairs clearance of secretions, with medical justification for the need and length of time the system will be utilized;
2. The patient has had exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract;
3. Where appropriate, the patient's medical record includes documentation of failure with flutter valve or acapella device therapy;
4. The patient does not already use a high frequency chest wall compression device (e.g., the Vest System, Medpulse Respiratory Vest System, Smart Wrap, Smart Vest).

C. Based upon our criteria and assessment of the peer-reviewed literature, high frequency chest wall compression devices (e.g., Monarch Airway Clearance System, AffloVest Vest Airway System, MedPulse Respiratory Vest System, Smart Vest) **and** intrapulmonary percussive ventilation devices (IPV) (e.g., Percussionaire, Percussinator, TXP, Impulsator) have been medically proven to be effective and, therefore, are considered **medically appropriate** when **ALL** of the following criteria are met:

1. The patient has a documented disease, that impairs clearance of secretions (e.g., cystic fibrosis, ciliary dyskinesia, or diffuse bronchiectasis);
2. The patient has a demonstrated need for the airway clearance device with exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract;

3. There is documentation of failure of or contraindication to standard treatments (e.g., pharmacotherapy, postural drainage, daily chest percussion, standard airway clearance devices [e.g., Flutter Valve or Acapella device therapy]);
4. Neither the patient's family nor other resources can adequately perform the needed bronchial drainage treatment (e.g., more than one child requires chest physiotherapy (CPT), or there is a valid medical reason that renders CPT inappropriate).

D. Based upon our criteria and assessment of the peer-reviewed literature, high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, when used as an alternative to CPT for any clinical situations other than in those indications listed above, do not improve patient outcomes when compared with conventional CPT and, therefore, are considered **not medically necessary**.

E. Based upon our criteria and the lack of peer-reviewed literature, other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use as an adjunct to chest physical therapy or use in other lung diseases, such as chronic obstructive pulmonary disease, are considered **investigational**.

II. Mechanical Percussors

A. Based upon criteria and assessment of the peer-reviewed literature, mechanical percussors (e.g., Frequencer, Fluid Flo Percussor) are considered **medically appropriate** when **BOTH** of the following are met:
1. the patient or operator of the powered percussor has received appropriate training,
2. no one competent to administer manual therapy is available.

III. Assisted Cough and Mechanical Insufflation Devices

A. Based upon our criteria, and assessment of the peer-reviewed literature, assisted cough and mechanical insufflation devices have been medically proven to be effective and, therefore, are considered **medically appropriate,** when **ALL** of the following criteria are met:
1. The patient is unable to cough to clear secretions effectively using available manual cough assistive techniques;
2. The patient experiences reduced peak cough expiratory flow (PCF) (falls below 300 lpm);
3. The patient's respiratory status is compromised with a history of high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease;
4. The patient has no contraindications for using cough assist devices include but are not limited to, a history of bullous emphysema, or susceptibility to pneumothorax or pneumomediastinum (lung barotrauma injury). Patients with cardiovascular instability should be cautious when using such devices.

IV. Repair and/or replacement of a medically necessary airway clearance device and/or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:
1. date of device initiation;
2. manufacturer warranty information; **and**
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **and** one of the following apply:

B. Repair of the currently used device when **all** of the following are met:
1. it is no longer functioning adequately;
2. inadequate function interferes with activities of daily living; **and**
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **or**

C. Replacement of the currently used device when the following are met:
1. it is no longer functioning adequately; **and either**
2. has been determined to be non-repairable; **or**
3. the cost of the repair is more than the replacement cost.

V. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. The replacement of properly functioning airway clearance device and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

*Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services*

## POLICY GUIDELINES

I. Prior authorization and coverage for an airway clearance device is contract dependent, unless mandated by federal or state mandate.

II. Referral for an airway clearance device must be generated by a pulmonologist.

## DESCRIPTION

Maintaining good bronchial hygiene in chronic pulmonary conditions can be a challenge in some patients. In healthy persons secretions in the lungs are moved by action of the cilia. When this clearance mechanism is ineffective in patients, such as those with weak respiratory musculature, ineffective cough or excessive tenacious secretions, chest physiotherapy (CPT) becomes necessary.

The standard method of CPT is manual percussion and postural drainage. In conditions such as cystic fibrosis, excessive tenacious secretions necessitate routine CPT to prevent airway obstruction leading to secondary infection, which is the principal cause of morbidity and mortality. At home, manual CPT is administered to the patient by a trained adult one to three times per day for 20-30 minutes per session. Manual CPT requires assistance by another person, thereby making independent living or the lack of a competent caregiver, a barrier to achieving the standard of care in some persons with cystic fibrosis.

Impairment of cough and airway clearance due to muscle weakness, glottic dysfunction, and low lung volumes increases respiratory morbidity and mortality risk. Thus, airway clearance techniques were considered a high priority for people diagnosed with a neuromuscular disease (NMD), since respiratory failure is a significant concern (Khan et al., 2023). There are several alternative methods available to support good bronchial hygiene in persons who have chronic pulmonary conditions and who are unable to comply with a prescribed regime of pulmonary therapy.

The following are alternatives to daily percussion and postural drainage, also known as chest physical therapy, to promote bronchial secretion drainage and clearance. Daily percussion and postural drainage need to be administered by a physical therapist or another trained person. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles.

I. Oscillatory Devices

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extra-thoracic. Some devices require the active participation of patients.

A. A high-frequency chest wall compression device is a mechanical form of chest physiotherapy. The technique assists with mucociliary clearance by altering airflow patterns and reducing sputum viscosity. The system is composed of a specially equipped vest, as well as a compressor that is mechanized to provide high-frequency chest compression. The system allows frequent inflation and deflation of the vest, compressing and releasing the chest wall to create airflow within the lungs. The vibrations, along with the increased airflow help to loosen mucus from the lungs.

The flutter valve, lung flute and acapella device are oral airway oscillatory devices that are hand-held and designed to facilitate clearance of mucus in hypersecretory lung disorders. Exhalations through either device result in oscillations of expiratory pressure and airflow, which vibrate the airway walls, decrease the collapsibility of the airways, and accelerate air flow, thereby facilitating movement of mucus up the airways. The flutter valve has not been shown to be effective in patients under age six years. These hand-held vibratory positive expiratory pressure (PEP) devices are an alternative to high-frequency chest wall compression devices.

The Vibralung Acoustical Percussor is an oral oscillatory device that is hand-held and designed to facilitate clearance of mucous in hypersecretory lung disorders. The device works by producing vibratory sound waves,

applying them during inspiration and exhalation across a broad spectrum of frequencies (from 5 to 1,200 Hz). This device is also an alternative to high-frequency chest wall compression devices.

B. The Percussionaire is an intrapulmonary percussive ventilation (IPV) device that assists in loosening tenacious secretions for expectoration. The IPV is patient-activated, and portable; the device delivers a high-volume aerosol solution while simultaneously delivering rapid bursts of air. Flow interruptions occur at a frequency of 3-5 Hz. Expiratory airflow is passive and relies on the elasticity of the respiratory system. It is the active expiration against the percussive phase of the device that leads to the maintenance of the positive expiratory pressure, which promotes airway patency, and prevention of early airway closure.

II. Assisted Cough and Mechanical Insufflation Devices

Coughing has three components: an inspiratory phase, which consists of an inhalation to greater than the resting end inspiratory volume and is an important part of airway defense; a compressive phase in which glottic closure is accompanied by increased intrathoracic pressure; and an expulsive phase, which results from sudden glottic opening. It is the sequence of these phases that move secretions from the bronchial wall to the pharynx for expectoration.

Neuromuscular conditions such as amyotrophic lateral sclerosis, poliomyelitis, myasthenia gravis and muscular dystrophies can cause respiratory muscle weakness, which may result in impairment of any or all phases of coughing.

Manually assisted cough and mechanical insufflation devices (e.g., In-Exsufflator, Cofflator, Cough-Alator) are portable machines that gradually apply a positive pressure to the airway then rapidly shift to a negative pressure, producing a high expiratory flow from the lungs. This stimulates a cough, which assists in clearing pulmonary secretions.

III. Mechanical Percussors

The purpose of percussion is to apply intermittent kinetic energy to the chest wall and lung. This is accomplished by rhythmically striking the chest and back with a cupped hand or mechanical device directly over lung segments. This technique loosens secretions in the airways and facilitates the drainage of secretions to the upper airways, where they can be expectorated using coughing and huffing techniques. Mechanical percussors can be compressed air- driven or electric.

## RATIONALE

In 2023, the American College of Chest Physicians published a clinical practice guideline and expert panel report on respiratory management of patients with neuromuscular weakness (Khan et al., 2023). Based on 128 studies, the panel generated 15 graded recommendations, one good practice statement, and one consensus-based statement, including the following non-inclusive list:

- For patients with NMD and chronic respiratory failure, we recommend using NIV for treatment (strong recommendation, very low certainty of evidence).
- For patients with NMD requiring NIV, we suggest individualizing NIV treatment to achieve ventilation goals (conditional recommendation, very low certainty of evidence).
- For patients with NMD and reduced cough effectiveness, we suggest manually assisted cough techniques independently or added to other modalities such as LVR (conditional recommendation, very low certainty of evidence).
- For patients with NMD and reduced cough effectiveness, which cannot be adequately improved with alternative techniques, we suggest the addition of regular mechanical insufflation-exsufflation (MI-E; cough assist device) (conditional recommendation, very low certainty of evidence).
- For patients with NMD and difficulties with secretion clearance, we suggest using high-frequency chest wall oscillation (HFCWO) for secretion mobilization. In addition, we suggest that HFCWO be combined with airway clearance therapies such as cough assistance or LVR (conditional recommendation, very low certainty of evidence).

A Cochrane systematic review of randomized controlled trials (RCTs) evaluated oscillatory devices for treating patients with Cystic Fibrosis (CF), addressing a variety of oscillatory devices, was last updated by Morrison and Milroy in 2020. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and QOL measures. Meta-

analysis was limited due to the variety of devices, outcome measures, and lengths of follow-up used. Reviewers concluded that there was a lack of evidence supporting the superiority of oscillatory devices versus any other form of physical therapy, that one device was superior to another, and that there is a need for adequately powered RCTs with long-term follow-up.

Lee et al. (2015) published the most current Cochrane review on airway clearance techniques for treating bronchiectasis. Of the 7 RCTs included, 6 were crossover trials. Five trials used a PEP device, one used high frequency chest wall oscillation, and 1 used postural drainage. Reviewers did not pool study findings due to heterogeneity among studies. Primary outcomes of interest were pulmonary exacerbations, hospitalizations for bronchiectasis, and QOL.

Several different pulmonary therapy devices have been investigated as an alternative to conventional CPT. A majority of the published data consists of small non-randomized cases studies with only short-term outcome measurements which do not suggest that these devices are associated with an increased health benefit as compared to conventional CPT.

Research has not shown that mechanical percussion is more effective than the manual method. However, mechanical percussion is an alternative to manual percussion to provide stimulus to the chest when there is no caregiver physically able to perform manual percussion on patient. Mechanical percussion reduces the physical effort required of the caregiver and can be self-administered to limited areas of the chest wall, but its success depends on the skill and reliability of the user.

To date, the most current guidelines on airway clearance therapies issued by the Cystic Fibrosis Foundation was published in 2009. Based on a systematic review of evidence, airway clearance therapies are recommended for all patients with cystic fibrosis for clearance of sputum, maintenance of lung function, and improved quality of life and no therapy has been demonstrated to be superior to others (level of evidence, fair: net benefit, moderate; grade of recommendation, B) (Flume et al., 2009). The Cystic Fibrosis Foundation also issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized, based on factors such as age and patient preference (Lahiri et al., 2016).

The U.S. Food and Drug Administration (FDA) has granted pre-market approval to a number of pulmonary therapy devices, including the Flutter Valve, the Vest Airway Clearance System, Vibralungand the Cofflator**.**

## CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

**CPT Codes**

| Code | Description |
|---|---|
| No specific code | |



**HCPCS Codes**

| Code | Description |
|---|---|
| A7025 | High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each |
| A7026 | High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each |
| E0480 | Percussor, electric or pneumatic, home model |

| Code | Description |
|---|---|
| E0481 | Intrapulmonary percussive ventilation system and related accessories |
| E0482 | Cough stimulating device, alternating positive and negative airway pressure |
| E0483 | High frequency chest wall oscillation system, includes all accessories and supplies, each |
| E0484 | Oscillatory positive expiratory pressure device, non-electric, any type, each |
| S8185 | Flutter device |

**ICD10 Codes**

| Code | Description |
|---|---|
| E84.0-E84.9 | Cystic fibrosis (code range) |
| G12.21 | Amyotrophic lateral sclerosis |
| G70.00-G70.01 | Myasthenia gravis (code range) |
| G71.0-G72.9 | Primary disorders of muscles and other and unspecified myopathies (code range) |
| G73.7 | Myopathy in diseases classified elsewhere |
| J47.0-J47.9 | Bronchiectasis (code range) |
| J96.00-J96.02 | Acute respiratory failure (code range) |
| J96.90-J96.92 | Respiratory failure, unspecified (code range) |
| M05.40-M05.49 | Rheumatoid myopathy with rheumatoid arthritis (code range) |
| M33.02 | Juvenile dermatomyositis with myopathy |
| M33.12 | Other dermatomyositis with myopathy |
| M33.22 | Polymyositis with myopathy |
| M33.92 | Dermatopolymyositis, unspecified with myopathy |
| M34.82 | Systemic sclerosis with myopathy |
| M35.03 | Sjogren syndrome with myopathy |
| Q33.4 | Congenital bronchiectasis |
| R06.00-R06.4 | Abnormalities of breathing (code range) |
| R06.81-R06.9 | Other abnormalities of breathing (code range) |

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*Key Article

## KEY WORDS

Acapella device, Cofflator, Flutter Valve, In-Exsufflator.

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) L33785 for High Frequency Chest Wall Oscillation Devices. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33785] accessed 10/03/24.

There is currently a Local Coverage Article (LCA) A52494 for High Frequency Chest Wall Oscillation Device. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52494] accessed 10/03/24.

There is currently a Local Coverage Determination (LCD) L33786 for Intrapulmonary Percussive Ventilation System. Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33786&ver=16&=] accessed 10/03/24.

There is currently a Local Coverage Determination (LCD) L33795 for Mechanical In-exsufflation Devices. Please refer to the following LCD website for Medicare Members: [ https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33795] accessed 10/03/24.