MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**AIRWAY CLEARANCE DEVICES: OSCILLATORY DEVICES (e.g. High frequency Chest Wall Compression, Flutter valve, Intrapulmonary Percussive Ventilator), MECHANICAL PERCUSSORS AND ASSISTED COUGH DEVICES (e.g. In-Exsufflator)**
Policy Number	**1.01.15**
Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. **Oscillatory Devices:**

A. Based upon our criteria and review 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 review 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 which impairs clearance of secretions such as cystic fibrosis, ciliary dyskinesia, or bronchiectasis, with medical justification for the need and length of time the system will be utilized; and
2. The patient has had exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract; and
3. Where appropriate, documentation of failure with flutter valve or Acapella device therapy is required; and
4. The patient does not already use a high frequency chest wall compression devices (e.g., the Vest® System, Medpulse Respiratory Vest System, Smart Wrap™, Smart Vest®).

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

1. The patient has a documented disease which impairs clearance of secretions such as cystic fibrosis, ciliary dyskinesia, or bronchiectasis, with medical justification for the need and length of time the system will be utilized;
2. Where appropriate, documentation of failure with flutter valve or Acapella device therapy is required;
3. The patient has had exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract; and

4. The patient's family or other resources cannot adequately perform the needed bronchial drainage treatment (e.g., more than one child requires chest physiotherapy/CPT, or a valid medical reason that renders CPT inappropriate).

D. Based upon our criteria and review of the peer-reviewed literature, *high-frequency chest wall compression devices* and *intrapulmonary percussive ventilation devices* are considered **not medically necessary** as an alternative to chest physical therapy for any clinical situations other than in those indications listed above; there is no clinical data to show that these devices provide any additional health benefit compared to conventional chest physical therapy.

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 their use in other lung diseases, such as chronic obstructive pulmonary disease, are considered **investigational**.

II. **Assisted Cough and Mechanical Insufflation Devices:**

A. Based upon our criteria, review of the peer-reviewed literature, and conversations with national experts, *Assisted Cough* and *Mechanical Insufflation Devices* have been medically proven to be effective and therefore, considered **medically appropriate** when ***ALL*** of the following criteria are met:
1. The patient is not only unable to cough, but also unable to clear secretions effectively using available manual cough assistive techniques;
2. The patient experiences reduced peak cough expiratory flow (PCF) which falls below 300 lpm; and
3. The patient's respiratory status is compromised because of a history of high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease.

B. **Contraindications** for using cough assist devices include but are not limited to: history of bullous emphysema, susceptibility to pneumothorax or pneumomediastinum (lung barotrauma injury). Patients with cardiovascular instability should be cautious when using such devices.

III. **Mechanical Percussors**:

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

Refer to Corporate Medical Policy# 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES

I. Prior authorization and referral for devices is contract dependent. Please contact the Provider Relations Department of your local Plan.

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

III. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

IV. Replacement of an airway clearance device such as a high frequency chest wall compression device with an upgraded model will be reviewed for medical necessity and eligible for coverage if:
A. The patient has experienced a change in his or her physiological condition;
B. Required repairs would exceed the cost of a replacement device or the parts that need to be replaced; or
C. There has been irreparable change in the device's condition or in a part of the device, due to normal wear and tear.

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, the principal cause of morbidity and mortality. At home, manual CPT is administered to the patient by a trained adult one to three times a day for 20-30 minutes per session. Manual CPT requires assistance by another person, thereby making independent living or the lack of competent caregiver, a barrier to achieving the standard of care in some persons with cystic fibrosis.

There are a number of alternative methods available to support good bronchial hygiene in persons with chronic pulmonary conditions who are unable to comply with a prescribed regime of pulmonary therapy.

I. **Oscillatory Devices:**

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 and 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* are oral airway oscillatory devices that are hand held and designed to facilitate clearance of mucus in hypersecretory lung disorders. Exhalations through either device results in oscillations of expiratory pressure and airflow, which vibrate the airway walls, decrease the collapsibility of the airways, and accelerate air flow, facilitating movement of mucus up the airways. The flutter valve has not been shown to be effective in patients under 6 years old. These hand-held vibratory 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* device is an intrapulmonary percussive ventilation (IPV) system to assist in loosening tenacious secretions for expectoration. The IPV is a patient-activated, portable device that 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 that consists of an inhalation to greater than the resting end inspiratory volume and is an important part of airway defense; a compressive phase where glottic closure is accompanied by increased intrathoracic pressure; and an expulsive phase resulting 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 amylotrophic 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, Coffaltor, 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 thereby stimulating a cough, which assists in clearing pulmonary secretions.

III. Mechanical Percussors:
The purpose of percussion is to intermittently apply 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 their drainage to the upper airways where they can be expectorated using coughing and huffing techniques. Mechanical percussors can be compressed air- driven or electric.

RATIONALE

A number of different pulmonary therapy devices (e.g., the Vest Airway Clearance System, IPV) 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.

The FDA has granted Premarket Market Approval (PMA) to a number of pulmonary therapy devices, including the Flutter Valve, the Vest Airway Clearance System, and the Cofflator.

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 strike the patient's chest with his hands. 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.

In April 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. They recommend airway clearance therapies for all patients with cystic fibrosis but state that no therapy has been demonstrated to be superior to others (level of evidence, fair: net benefit, moderate; grade of recommendation, B). They also issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized based on factors such as age and patient preference.

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.*

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

Code	Description
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussor ventilation system and related accessories
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High frequency chest wall oscillation air-pulse generator 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 dermatopolymyositis with myopathy
M33.12	Other dermatopolymyositis with myopathy
M33.22	Polymyositis with myopathy
M33.92	Dermatopolymyositis, unspecified with myopathy
M34.82	Systemic sclerosis with myopathy
M35.03	Sicca 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 for High Frequency Chest Wall Oscillation Devices. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-

details.aspx?LCDId=33785&ver=29&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQBAAAA&

There is currently a Local Coverage Determination for Intrapulmonary Percussive Ventilation System. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33786&ContrId=389&ver=7&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQAAAAA&

There is currently a Local Coverage Determination for Mechanical In-exsufflation Devices. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33795&ver=24&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQBAAAA&