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 and Mechanical Insufflation Devices (e.g., In-Exsufflator)**
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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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *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.* • *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.* • *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; and
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., 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 **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; and
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, there is no clinical data to show that high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices provide any additional health benefit, when compared with conventional CPT, and, therefore, are considered **not medically necessary** as an alternative to CPT for any clinical situations other than in those indications listed above.

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:**

Based upon our criteria and assessment of the 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.

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

A. Based upon our criteria, and assessment 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, are 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) (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, 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 and Investigational Services

POLICY GUIDELINES

I. Prior authorization and referral for airway clearance devices is contract dependent. Please contact the Customer Care (Member or Provider) Department to determine benefits available under a member's subscriber contract.

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

III. Coverage for Durable Medical Equipment is contract dependent unless mandated by federal or state mandates. Please refer to your Customer (Member/Provider) Service Department to determine contract coverage.

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.

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.

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, 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

Several 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 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, 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 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.

In its April 2009 guidelines on airway clearance therapies, the Cystic Fibrosis Foundation recommended, based on a systematic review of evidence, airway clearance therapies for all patients with cystic fibrosis, noting that no therapy has been demonstrated to be superior to others (level of evidence, fair: net benefit, moderate; grade of recommendation, B). 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.

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
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)

Code	Description
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&ver=40&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQBIAAA accessed 10/11/23.

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/details/lcd-details.aspx?LCDId=33786&ver=16&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQAIAAA& accessed 10/11/23.

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/details/lcd-details.aspx?LCDId=33795&ver=29&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQBIAAA& accessed 10/11/23.