
Subject:	High Frequency Chest Compression Devices for Airway Clearance	Publish Date:	01/04/2023
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Description

This document addresses the use of high frequency chest compression devices (HFCC) (such as the Vest™ Airway Clearance System or the Medpulse® Respiratory Vest System) as an alternative to conventional chest physical therapy to promote the clearance of respiratory secretions in individuals with impaired ability to cough or otherwise expel them on their own.

Note: Other types of mucous clearance systems are not addressed within this document (for example, the Flutter® Mucous Clearance System, the Acapella® Vibratory PEP Therapy System, etc.). See Definitions section for further information.

Note: For information regarding intrapulmonary percussive ventilation devices, please refer to:

- DME.00012 Intrapulmonary Percussive Ventilation Devices

Clinical Indications

Medically Necessary:

Initial use of a high frequency chest compression device (see index for examples) is considered **medically necessary** when **ALL** of the following are met:

- A. The device is cleared by the U.S. Food and Drug Administration; **and**
- B. There is documented need for airway clearance; **and**
- C. The individual has **one** of the following diagnoses:
 1. Cystic fibrosis; **or**
 2. Chronic bronchiectasis; **or**
 3. Chronic neuromuscular disorder affecting the ability to cough or clear respiratory secretions with prior history of pneumonia or other significant worsening of pulmonary function; **and**
- D. There is documentation of i) failure of or ii) inability to use other airway clearance therapies including manual chest physical therapy due to **one** or more of the following:
 1. There are 2 or more individuals with cystic fibrosis, chronic bronchiectasis, or chronic neuromuscular disorder (meeting criteria above) in the family; **or**
 2. The caregiver is unable (physically or mentally) to perform chest physical therapy at the required frequency; **or**
 3. There is no available parental or partner resource to perform chest physical therapy; **and**
- E. There is documentation of a trial during which the affected individual and the family (when applicable) demonstrates ability to comply (see the following statement for details).

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Continued use of a high frequency chest compression device is considered **medically necessary** when ongoing use, (that is, compliance with use) is documented at 6 month to 12 month intervals. (Note: For high frequency chest compression devices with usage meters, documentation should reflect use, in general, at least 67% of the prescribed time).

Not Medically Necessary:

High frequency chest compression devices are considered **not medically necessary** when the above criteria have not been met.

High frequency chest compression device replacement or upgrade is considered **not medically necessary** when requested for convenience or to upgrade to newer technology when the current components remain functional.

All other indications for high frequency chest compression are considered **not medically necessary**, including, but not limited to, chronic obstructive pulmonary disease.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Chest physiotherapy (CPT), which is also known as percussion and postural drainage (P/PD), is traditionally seen as the standard of care of secretion clearance methods for individuals with excessive or retained lung secretions. Currently, there are a variety of mucus clearance devices that have been evaluated as alternatives to P/PD. Studies related to these devices have not provided adequate data to permit scientific conclusions regarding the relative efficacy of alternative oscillatory therapies compared to CPT, which is the standard therapy for mucus clearance in

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individuals with cystic fibrosis (CF) and other diseases associated with mucus retention. However, because some afflicted individuals may not have an option for CPT, this document outlines criteria for medical necessity in the use of U.S. Food and Drug Administration (FDA)-cleared HFCC devices, such as the Vest Airway Clearance System, (Hill-Rom, St. Paul, MN; previously manufactured by Advanced Respiratory, Inc., St. Paul, MN), the SmartVest Airway Clearance System (Electromed, Inc., New Prague, MN), the inCourage™ System (RespirTech, Inc., St. Paul, MN), and the Medpulse Respiratory Vest System (Electromed, Inc., Minnetonka, MN), as an alternative therapy for selected individuals.

The FDA cleared the original Vest Airway Clearance System in 1988. The approved indications for the current model (Model 105), which is substantially equivalent to the predicate device, are:

to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.

Several earlier versions included the ThAIRapy™ Vest System (Model 101, Model 102) and the ABI Vest™ Airway Clearance System (Model 103), amongst others (Advanced Respiratory, Inc. St. Paul, MN).

According to AARC 1991 Clinical Practice Guidelines for Postural Drainage Therapy, postural therapy requires assessment of potential benefits versus potential risks. The guidelines indicate contraindications that exist for external manipulation of the thorax. Contraindications include, but may not be limited to, unstable head or neck injury; active hemorrhage with hemodynamic instability; subcutaneous emphysema; recent epidural, spinal fusion or spinal anesthesia; recent skin grafts or flaps on the thorax; burns, open wounds, and skin infections of the thorax; recently placed transvenous pacemaker or subcutaneous pacemaker; suspected pulmonary tuberculosis; lung contusion; bronchospasm; osteomyelitis of the ribs; osteoporosis; coagulopathy; and complaint of significant chest wall pain.

Cystic Fibrosis

HFCC devices have shown improved lung function and sputum clearance in many who are afflicted with CF with few adverse effects. However, the therapy has not been shown to be superior to conventional CPT in short-term studies, and its impact on long-term prognosis is unknown. In addition, it is not clear from the clinical studies which subjects would derive the most benefit from this therapy or at what time during the course of the disease HFCC should be initiated. Interpretations of the data derived from the clinical trials of HFCC for CF are complicated by issues in study design, small sample sizes, inadequate length of follow-up, heterogeneity of study subjects, and lack of control for confounding variables such as concurrent treatment, disease severity, respiratory functions variability, and age. Moreover, there remain questions of the validity and reliability of outcome measures such as sputum weight and respiratory function indexes for the determination of therapeutic efficacy.

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The Cystic Fibrosis Foundation commissioned a systematic review to examine the evidence surrounding the use of airway clearance therapies (ACTs) for treating CF. Seven unique reviews and 13 additional controlled trials were deemed eligible for inclusion. Recommendations for use of the ACTs were made, balancing the quality of evidence and the potential harms and benefits. The committee determined that:

Although there is a paucity of controlled trials that assess the long-term effects of ACTs, the evidence quality overall for their use in CF is fair and the benefit is moderate... There are no ACTs demonstrated to be superior to others, so the prescription of ACTs should be individualized (Flume, 2009).

The Cystic Fibrosis Foundation recommends that age alone not limit access to HFCC devices, so long as the individual can be properly supervised and tolerates the treatment.

Bronchiectasis

Within the American College of Chest Physicians (ACCP) CHEST Expert Panel Report on Treating Cough Due to Non-CF and CF Bronchiectasis With Nonpharmacologic Airway Clearance, the ACCP determined that the evidence supporting the use of airway clearance techniques, including HFCC, in the treatment of individuals with productive cough due to bronchiectasis was low, and the cough panel was not able to make recommendations; however, they made consensus-based suggestions. The cough panel suggests that individuals with productive cough due to bronchiectasis be taught airway clearance techniques, and that all airway clearance techniques and frequency be individualized due to the different types of techniques, disease severity, and amount of secretions (Hill, 2018).

Several studies have shown high-frequency chest wall oscillation (HFCWO) to improve both pulmonary function and quality of life related parameters in individuals with non-CF bronchiectasis. Nicolini and colleagues (2013) conducted a randomized controlled trial in which 30 individuals with non-CF bronchiectasis were divided into three treatment groups (10 subjects each): HFCWO using the Vest Airway Clearance System, traditional techniques of CPT including positive expiratory pressure, and medical therapy only (control group). Compared to CPT, HFCWO produced improvement in parameters of lung function associated with bronchial obstruction (forced vital capacity and forced expiratory volume 1 sec, $p \leq 0.006$ and $p \leq 0.001$, respectively), and in dyspnea. Improvements in the Breathlessness, Cough, and Sputum Scale (BCSS) and COPD Assessment Test (CAT) were also significant in HFCWO vs. CPT (both $p \leq 0.001$). In a follow-up study, Nicolini and colleagues (2022) performed another randomized controlled trial in which 60 subjects with bronchiectasis were divided into three groups. Two groups were treated with HFCWO using either the SmartVest or RespIn 11, and one group (control) received medical therapy only. Subjects in both of the HFCWO groups showed significant improvements in tests of dyspnea, cough and quality of life evaluations (BCSS and CAT) compared to the control group, but not in pulmonary function tests or arterial blood gas analysis. Subjects in the RespIn 11 group had a significantly reduced number of acute exacerbations at 6 and 12 months after the end of treatment in comparison with the control group. The authors concluded that use of HFCWO devices improves the health and quality of life in individuals with bronchiectasis.

In a retrospective study of data from 2596 adult individuals with non-CF bronchiectasis, Barto and colleagues (2020) evaluated hospitalization patterns before and after initiation of HFCWO therapy, as well as antibiotic use and self-reported metrics of quality of life. After starting HFCWO therapy, the number of subjects who had at least

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one respiratory-related hospitalization decreased from 49.1% in the year before to 24.0% in the year after starting therapy ($p<0.001$). The use of oral antibiotics for respiratory conditions decreased from 57.7% of subjects upon initiation of therapy to 29.9% within 1 year ($p<0.001$). Individuals who subjectively rated their respiratory health as good to excellent increased from 13.6% upon initiation of therapy to 60.5% in 1 year ($p<0.001$); those who rated the ability to clear their lungs as good to excellent increased from 13.9% to 76.6% ($p<0.001$). The conclusion was that individuals with bronchiectasis showed improved health and quality of life outcomes associated with the initiation of HFCWO therapy that was sustained for 1 year.

Neuromuscular Diseases

Difficulty clearing pulmonary secretions is common in individuals with neuromuscular conditions such as cerebral palsy, muscular dystrophy and amyotrophic lateral sclerosis (ALS). A number of studies have evaluated the use of HFCWO therapy in improving respiratory health in these individuals. In 2010, Yuan and colleagues conducted a prospective randomized controlled trial of HFCWO and CPT with pediatric participants who had cerebral palsy ($n=9$) or neuromuscular diseases including muscular dystrophy ($n=14$). They found that there was a significant increase in maximum saturation level of oxygen in hemoglobin post therapy in the HFCWO group ($p=0.01$). They also observed a trend toward fewer hospitalizations for respiratory infections in individuals receiving HFCWO compared to those receiving standard CPT ($p=0.09$). Lange and colleagues (2006) investigated changes in respiratory function in individuals with ALS after using HFCWO in a 12-week randomized controlled trial. A total of 35 subjects were in the trial: 19 used HFCWO and 16 were untreated. At 12 weeks, subjects in the HFCWO group reported a decrease in breathlessness ($p=0.048$). Lechtzin and colleagues (2016) performed a larger cohort study comparing healthcare claims before and after initiation of HFCWO in 426 individuals (children and adults) with neuromuscular diseases including muscular dystrophy, spinal muscular atrophy, multiple sclerosis, quadriplegia, and ALS. Total medical costs per individual per month decreased by \$1,949 (18.6%) after initiation of HFCWO ($p=0.002$). There was also a significant reduction in costs for hospitalizations ($p=0.001$) and pneumonia treatment ($p=0.03$) after use of HFCWO. These data support the use of HFCWO for individuals with neuromuscular disease and difficulty clearing respiratory secretions.

Other applications of HFCC devices, including but not limited to their use as an adjunct to CPT or their use in diseases other than CF, chronic bronchiectasis, or chronic neuromuscular disorders, as specified in this document, are considered not medically necessary since the scientific evidence does not permit the conclusion that the technology improves the net health outcome.

Definitions

Bronchiectasis: A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or from a congenital condition.

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Bronchitis: An inflammation of the upper airways associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last 2 or more years, a person has been coughing up some mucus every day for at least 3 months out of the year.

Chest physiotherapy (CPT) (also known as chest physical therapy): The use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is to improve mucociliary clearance and pulmonary function in order to reduce the risk of infection and lung damage.

Cystic fibrosis (CF): An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF.

Flutter mucous clearance device (AXCAN Scandipharm, Inc., Birmingham, AL): Another type of oscillatory device which is handheld and resembles a pipe with a plastic mouthpiece on one end that the user exhales into. On the other end of the pipe, a stainless steel ball rests inside a plastic circular cone. When the individual exhales into the device, the ball rolls and moves up and down, creating an opening and closing cycle over a conical canal. The cycle repeats itself many times throughout each exhalation intending to produce oscillations of endobronchial pressure and expiratory airflow that will vibrate the airway walls and loosen mucus so that it can be easily expectorated (coughed up) by the user. The Flutter device has 510(k) status with the FDA, although it has not been shown, in well-designed trials, to significantly change respiratory assessment parameters or pulmonary function. Some individuals may prefer this method over other therapies. A similar oscillatory positive airway pressure device is the Acapella (Smiths Medical, Watford, UK), which uses a counterweighted plug and magnet to create air flow oscillation. It has been noted that the Acapella device performance is not gravity-dependent and, as such, may be easier to use for some individuals. (Note: The Flutter and Acapella devices are not chest compression devices and require active user participation to function properly as positive expiratory pressure oscillatory [PEP] devices.)

Frequencer: A device that provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. It induces oscillatory sound waves in the chest by means of an electro-acoustical transducer (referred to as the "Power Head") which is placed externally on the user's chest. The Power Head is connected to a frequency generator which is capable of producing frequencies between 20 and 100 Hz. and induces sound waves in the user's chest for the purpose of loosening mucus deposits.

High-frequency chest compression (HFCC): A treatment designed to help improve secretion clearance for individuals suffering from excessive or retained lung secretions. Currently, several conventional therapies, such as percussion on the thorax and postural drainage (P/PD), are used to produce this effect, particularly in cystic fibrosis (CF). These individuals have difficulty clearing lung secretions which leads to difficulty in breathing, infection, hypoxemia, and bronchiectasis.

High-frequency chest wall oscillation (HFCWO): The mechanized technology employed by HFCC. HFCWO involves air pulses generated at various frequencies that are transmitted through a vest and compress the user's chest.

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Vest Airway Clearance System (also known as the ABI Vest, ThAIRapy Vest, or the ThAIRapy Bronchial Drainage System®): HFCC devices that consist of an air generator and an inflatable vest that covers the thorax and provides high frequency chest wall oscillation. Large-bore tubing connects the vest to the air-pulse generator which creates pressure pulses that cause the vest to inflate and deflate against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions. The device is designed for self-therapy and consists of a large volume, variable frequency, air pulse delivery system and a nonstretchable inflatable vest worn by the user. Pressure pulses are controlled by the user and applied during expiration. This device has 510(k) clearance status with the FDA.

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This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

High Frequency Chest Compression Devices for Airway Clearance

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- ABI Vest Cystic Fibrosis High Frequency Chest Compression (HFCC)
- AffloVest®
- Frequencer
- inCourage System
- Medpulse Respiratory Vest System
- Monarch™ Airway Clearance System
- Oscillatory Devices
- Respin11® Bronchial Clearance system
- SmartVest Airway Clearance System
- ThAIRapy Bronchial Drainage System
- ThAIRapy Vest
- Vest Airway Clearance System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
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Reviewed	11/10/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References and Websites sections.
Revised	11/11/2021	MPTAC review. Removed the word “initial” and simplified criteria statement for criteria E under MN section. Removed criteria B from NMN section and incorporated information into discussion section. Updated References and Website sections.
Reviewed	11/05/2020	MPTAC review. Updated References and Websites sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	01/24/2019	MPTAC review. Updated Discussion/General Information, Definitions, References, and Websites for Additional Information sections.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS updates.
New	01/25/2018	MPTAC review. Initial document development. Moved HFCC content of DME.00012 “Oscillatory Devices for Airway Clearance including High Frequency Chest Compression and Intrapulmonary Percussive Ventilation Devices” to new clinical utilization management guideline titled “High Frequency Chest Compression Devices for Airway Clearance.”

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