

**Policy terminated because coverage is provided under  
NCHC Durable Medical Equipment and Supplies**

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## **1.0 Description of the Procedure, Product, or Service**

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for recipients with cystic fibrosis. There are several types of devices including high-frequency chest compression with an inflatable vest and oscillating positive expiratory pressure devices, such as the FLUTTER and Acapella devices. Oscillatory devices are also proposed for other respiratory conditions such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extra-thoracic. Some of the devices require the active participation of the recipient. These include oscillating positive expiratory pressure devices, such as FLUTTER and Acapella, in which the recipient exhales multiple times through a device. The FLUTTER device is a small pipe-shaped, easily portable hand-held device, with a mouthpiece at one end. It contains a high-density stainless steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs, resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create air flow oscillation.

Other airway clearance techniques require active recipient participation; these include autogenic drainage and positive expiratory pressure therapy. Autogenic drainage, developed in Belgium and commonly used in Europe, consists of a series of controlled breathing exercises and does not involve an oscillatory device. Positive expiratory pressure therapy requires recipients to exhale through a resistor to produce positive expiratory pressures during a prolonged period of exhalation. It is hypothesized that the positive pressure supports the small airway such that the expiratory airflow can better mobilize secretions.

In contrast, high-frequency chest wall compression devices (e.g. the Vest™ Airway Clearance System, formerly known as the ABI Vest® or the ThAIRapy Bronchial Drainage System®) are passive oscillatory devices designed to provide airway clearance without the active participation of the recipient. The Vest™ Airway Clearance System provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator 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 Percussionaire device delivers intrapulmonary percussive ventilation (IPV) and is another type of passive oscillatory device. This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

All of the above techniques can be used as alternatives to daily percussion and postural drainage (P/PD), also known as chest physical therapy or chest physiotherapy, in recipients with cystic fibrosis. P/PD needs to be administered by a physical therapist or another trained adult in the home, typically a parent if the recipient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who wish to lead independent lifestyles. Oscillatory devices can also potentially be used by recipients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

### 1.1 Regulatory Status

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process including the following:

- a. The Bird IPV Noncontinuous Ventilator (Percussionaire Corp) in 1989.
- b. FLUTTER Mucus Clearance Device in 1994. The FLUTTER device is currently marketed in the United States by Axcan.
- c. The ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by the FDA—most recently a fifth generation device. The device is now known as the Vest System and it is manufactured by Hill-Rom.
- d. The Acapella device (DHD Healthcare) in 1999.
- e. The RC Cornet Mucus Clearing Device (PARI Respiratory Equipment) in 1999.

## 2.0 Eligible Recipients

### 2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

**Note:** Most children will be able to get all the services they need under the core (basic) plan of NC Health Choice. A child who qualifies as having special needs may be able to receive additional services not covered by the core plan.

## 3.0 When the Procedure, Product, or Service Is Covered

### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

- a. Oscillatory devices (including flutter devices) for the treatment of cystic fibrosis are covered under the NC Health Choice Program when they are determined to be medically necessary.
- b. Use of the FLUTTER® valve or Acapella device may be considered medically necessary in recipients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.
- c. High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices may be considered medically necessary in recipients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (refer to **Subsection 3.3**, Medical Policy Guidelines) including chest computed tomography scan when standard chest physiotherapy has failed OR standard chest physiotherapy is unavailable or not tolerated.
- d. In considering the chest wall compression and IPV devices, there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments, i.e., the recipient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physiotherapy and, if appropriate, use of the FLUTTER device), or valid reasons why standard chest physiotherapy cannot be performed, such as inability of the caregiver to perform it.

### 3.3 Policy Guidelines

High frequency chest wall oscillation may be considered medically necessary when ALL of the following criteria are met:

- a. The device is used for a recipient with cystic fibrosis or chronic bronchiectasis who requires effective chest physiotherapy when conventional manual CPT is unavailable, ineffective, or not tolerated. Recipients benefitting most from the device are adolescents and older recipients due to lifestyle issues in which manual conventional CPT is essentially unavailable. Recipients should demonstrate high motivation and compliance with use of the device.
- b. For the purposes of this policy, chronic bronchiectasis is defined by daily productive cough for at least 6 continuous months, or more than two exacerbations per year, requiring antibiotic therapy and confirmed by high resolution or spiral chest CT scan.
- c. The device is prescribed for recipients who actually do have bronchopulmonary secretions to mobilize. It should not be used prophylactically to prevent onset of respiratory symptoms.
- d. The recipient has high frequency chest wall oscillation prescribed by either a pulmonologist or a cystic fibrosis clinic.
- e. Recipient has a documented successful 4 month trial period using the high frequency chest wall oscillation device. This includes written confirmation that the recipient has demonstrated sufficient and appropriate usage of the device during the trial period. Appropriate usage is defined as daily treatment sessions for an absolute minimum of 15 minutes per session.

- f. Therapy with the device is closely supervised and monitored by the prescribing physician on a monthly basis to ensure compliance and continued efficacy. Monthly symptom assessment results and treatment compliance analyses are closely monitored by the prescribing physician.
- g. The recipient demonstrates to the prescribing physician that the device has proven efficacy and that the recipient will be compliant and accepting of its use in the home. Documentation of efficacy is critical because recipients with severe small airway obstruction and debilitation may be unable to cough effectively, regardless of the mode of CPT.

Note: A lifetime warranty is included with the purchase of The Vest® airway clearance system and the Medpulse SmartVest®.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### 4.2 Specific Criteria

Oscillatory devices for the treatment of respiratory conditions are not covered in the following situations:

- a. High-frequency chest wall compression devices are considered not medically necessary as an alternative to chest physical therapy in recipients with cystic fibrosis or chronic bronchiectasis in any other clinical situations; there are no clinical data to show that these devices provide any additional health benefit compared to conventional chest physical therapy in situations other than those specified here.
- b. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including their use as an adjunct to chest physical therapy or their use in other lung diseases, such as COPD, are considered investigational.

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval is required for oscillatory devices for the treatment of respiratory conditions.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
October 31, 2011	Throughout	Policy Termination. Coverage for this policy is provided by NCHC policy 2011.09, Medical Equipment and Supplies.

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

HCPCS - Codes
A7025
A7026
E0483
E0484
E0481
S8185

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Home

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.

After the initial authorization and purchase of the vest system, recipients will receive all replacements needed to operate the HFCWO system. All replacement costs are included in the payment of the original HFCWO system. This includes, but is not limited to refit vests, hoses, and the generator.