

**Policy #: 120**

**Original policy date: 11/1996**  
**Revised date: 9/1/2009**

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**Title**

**Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders**

**Description**

Cystic fibrosis (CF) is an autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection, the principal causes of the morbidity and mortality of cystic fibrosis.

A variety of mucus clearance techniques have been investigated as methods to increase the amount of expectorated sputum, maintain pulmonary function, and decrease the incidence of acute exacerbations of CF. Daily percussion and postural drainage (P/PD) is the most commonly used secretion clearance technique. A physical therapist or another trained adult in the home, typically a parent, may administer P/PD if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who wish to lead independent lifestyles.

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®) is an oscillatory device designed to provide self-administered airway clearance and has been investigated as an alternative to P/PD. 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, another oscillatory device being studied as an alternative to P/PD, delivers intrapulmonary percussive ventilation (IPV). This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer. IPV can be self-administered by patients, who breathe through the mouthpiece, then cough to clear the loosened secretions.

The FLUTTER® device is another oscillatory device that has been used in patients with cystic fibrosis. It 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 techniques 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. Positive expiratory pressure therapy requires patients 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.

Of the techniques described above, P/PD, the Percussionaire device and the Vest™ Airway Clearance System are passive techniques, not requiring the participation of the patient. In contrast, autogenic drainage, the FLUTTER® device, and positive end expiratory pressure require continuous active participation by the patient.

Oscillatory devices have been used in other respiratory disorders to promote bronchial secretion drainage and clearance, such as bronchiectasis and chronic obstructive pulmonary disorder (COPD).

**When services are covered for commercial products (excluding Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx)**

We cover **high-frequency chest wall compression devices** (Vest™ Airway Clearance System) as an alternative to chest physical therapy for airway clearance in patients with cystic fibrosis or chronic diffuse bronchiectasis when standard chest physiotherapy has failed.<sup>1</sup>

Examples:

- The patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite percussion and postural drainage, *or*
- Standard chest physiotherapy is unavailable or not tolerated.

We cover the use of the **FLUTTER® valve or Acapella® device** in patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.<sup>1</sup>

**When services are not covered for commercial products (excluding Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx)**

We do not cover **high-frequency chest wall compression devices** as an alternative to chest physical therapy in patients 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 these situations.<sup>1</sup>

We do not cover other applications of **high-frequency chest wall compression devices**, including, but not limited to the following, since their use is considered investigational<sup>1</sup> and do not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #350:

- Use as an adjunct to chest physical therapy, *or*
- Use in other lung diseases, i.e. chronic obstructive pulmonary disease.

We do not cover **intrapulmonary percussive ventilation devices**, i.e. the Percussionaire® device, in the treatment of patients with chronic pulmonary diseases including cystic fibrosis and bronchiectasis since they are considered investigational<sup>1, 2</sup> and do not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #350.

**When services are covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx**

We cover **high-frequency chest wall compression devices** (Vest™ Airway Clearance System) for **Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx** members who meet one of the following criteria:<sup>3, 4</sup>

- There is a diagnosis of cystic fibrosis,
- There is a diagnosis of bronchiectasis,
  - o Characterized by daily productive cough for at, least six continuous months or frequent exacerbations (i.e. more that two per year) requiring antibiotic therapy, and
  - o Confirmed by high resolution, spiral or standard CT scan.

**OR**

- The patient has one of the following neuromuscular disease diagnoses:
  - o Post polio

- o Acid maltase deficiency
- o Anterior horn cell disease
- o Multiple sclerosis
- o Quadriplegia
- o Hereditary muscular dystrophy
- o Myotonic disorders
- o Other myopathies
- o Paralysis of the diaphragm

**AND**

- Well documented failure of standard treatments to adequately mobilize retained secretions.

**Note:** For diagnoses that are considered medically necessary for **Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products**, see footnote 3.

We cover the use of the **FLUTTER® valve or Acapella® device** in patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.<sup>1</sup>

**When services are not covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx**

We do not cover **intrapulmonary percussive ventilation devices**, i.e. the Percussionaire® device, in the treatment of patients with chronic pulmonary diseases including cystic fibrosis and bronchiectasis since they are considered investigational<sup>1, 5</sup> and do not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #350.

**Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

**For services already billed**

Blue Cross Blue Shield of Massachusetts  
 Provider Appeals  
 PO Box 986065  
 Boston, MA 02298

**Prior to performance of service**

Blue Cross Blue Shield of Massachusetts  
 Case Creation/Medical Policy  
 One Enterprise Drive  
 Quincy, MA 02171  
 Tel: 1-800-327-6716  
 Fax: 1-888-641-5330

**Authorization Information:**

**For Managed Care members:**

- No authorization is required for this service; see *Managed Care Guidelines for additional requirements*.

**For Indemnity and PPO members:**

- No authorization is required for this service; see *Indemnity and PPO Guidelines for additional requirements*.

**Managed Care Guidelines:**

All authorization requirements are determined by the individual’s subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

### **Indemnity and PPO Guidelines:**

**All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;**

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

### **Other information**

For our Medical Technology Assessment Guidelines, see document #350.

### **Coding information**

*Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

#### **HCPCS codes**

- **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
- **E0483:** high frequency chest wall oscillation air-pulse generator system (includes hoses and vest), each
- **E0484:** oscillatory positive expiratory pressure device, non-electric, any type, each
- **S8185:** flutter device

The following item is considered non-covered for commercial products and for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRX products since it does not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #350:

#### **HCPCS code**

- **E0481:** intrapulmonary percussive ventilation system and related accessories

### **Policy update history**

Revised 11/96 to exclude coverage for ThAIRapy Vest<sup>®</sup>. Updated 5/99 to exclude coverage for the flutter device, effective 10/1/99. Update 1/00 to include billing information for flutter device; to add additional background information on high-frequency oscillation vests; and to include 2 BCBS national codes. Updated 3/01 to include individual consideration guidelines for ThAIRapy vest for patients with

no option for chest physical therapy. Updated 12/03 to include coverage for high frequency chest wall oscillation devices for Blue Care 65 (Medicare HMO Blue) members, effective 10/1/2003. Updated 6/05 to include additional oscillatory devices (i.e. Acapella device, and Percussionaire device), correction made in a change to the new product name for ThAIRapy vest noted under sections: when services are covered and when services are not covered, and references added based on BCBSA National medical policy, #1.01.05. Updated 3/09 based on a comparison review of BCBSA national medical policy, *Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders*; BCBSA coverage and non-coverage language has changed. BCBSMA published in Provider Focus-June/July'09 that a new medical policy document will be effective 9/1/2009; the new medical policy will benchmark BCBSA's new coverage language. New policy, #120 issued 9/09, effective 9/1/2009. Information pertaining to oscillatory and flutter devices was previously referenced on medical policy #377, Respiratory Devices.

## References

### References for footnote 1:

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### Footnotes

<sup>1</sup> Based on the BCBSA national policy 1.01.15, Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Disorders, issued 12/2008.

<sup>2</sup> Based on the Region A DMERC Local Coverage Determination, Intrapulmonary percussive Ventilation system, #L5051. [http://www.medicarenhic.com/dme/medical\\_review/mr\\_lcds/mr\\_lcd\\_current/L5051\\_2007-07-01\\_PA\\_2005-07.pdf](http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L5051_2007-07-01_PA_2005-07.pdf)

<sup>3</sup> Based on the Region A DMERC Local Coverage Determination, High Frequency Chest Wall Devices, #L12870. [http://www.medicarenhic.com/dme/medical\\_review/mr\\_lcds/mr\\_lcd\\_current/L12870\\_2008-10-01\\_PA\\_2008-10.pdf](http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L12870_2008-10-01_PA_2008-10.pdf)

<sup>4</sup> ICD-9-CM diagnoses codes that support the medical necessity for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products for coverage of high frequency chest wall devices in accordance with the Region A DMERC LCD, #L12870.

- 011.50-011.56, Tuberculous bronchiectasis unspecified examination - Tuberculous bronchiectasis, tubercle bacilli not found by bacteriological or histological examination, but tuberculosis confirmed by other methods [inoculation of animals]
- 138, Late effects of acute poliomyelitis
- 277.00, Without mention of meconium ileus
- 277.02, With pulmonary manifestations
- 277.6, Other deficiencies of circulating enzymes
- 335.0-335.9, Werdnig-Hoffmann disease - Anterior horn cell disease, unspecified
- 340, Multiple sclerosis
- 344.00-344.09, Quadriplegia unspecified - Other
- 359.0, Congenital hereditary muscular dystrophy

- 359.1, Hereditary progressive muscular dystrophy
- 359.21-359.29, Myotonic muscular dystrophy - Other specified myotonic disorder
- 359.4-359.6, Toxic myopathy - Symptomatic inflammatory myopathy in diseases classified elsewhere
- 359.89, Other myopathies
- 494.0, Bronchiectasis without acute exacerbation
- 494.1, Bronchiectasis with acute exacerbation
- 519.4, Disorders of diaphragm
- 748.61, Congenital bronchiectasis

<sup>5</sup> Based on the Region A DMERC Local Coverage Determination, Intrapulmonary percussive Ventilation system, #L5051. [http://www.medicarenhic.com/dme/medical\\_review/mr\\_lcds/mr\\_lcd\\_current/L5051\\_2007-07-01\\_PA\\_2005-07.pdf](http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L5051_2007-07-01_PA_2005-07.pdf)