I. Description

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for patients 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 patient. These include oscillating positive expiratory pressure devices, such as Flutter and Acapella, in which the patient exhales multiple times through a device. The Flutter device is a small pipe-shaped, easily portable handheld 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 airflow oscillation.

Other airway clearance techniques require active patient participation. For example, autogenic drainage and active cycle of breathing technique both involve a combination of breathing exercises performed by the patient. Positive expiratory pressure (PEP) 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.

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, Smart Vest) are passive oscillatory devices designed to provide airway clearance without the active
High Frequency Chest Wall Oscillation Devices

participation of the patient. 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 patients 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 patient 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 patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

II. Criteria/Guidelines

The Vest™ is covered when all of the following criteria are met (subject to the Limitations/Exclusions and Administrative Guidelines):

A. The device must be recommended by a pulmonologist.
B. The patient has a diagnosis of cystic fibrosis or chronic diffuse bronchiectasis. Chronic bronchiectasis is defined as daily productive cough for at least six continuous months or more than two exacerbations per year requiring antibiotic therapy and confirmed by high resolution or spiral chest computed tomography scan.
C. The patient has been hospitalized more than once for pulmonary related conditions within the past two years.
D. Recent pulmonary function studies demonstrate forced expiratory volume (FEV-1) less than 80 percent of predicted and forced vital capacity (FVC) of less than 50 percent of predicted.
E. Caregiver is unable to provide effective chest percussion and postural drainage.
F. Alternative therapy (e.g., daily percussion and postural drainage, autologous drainage, positive end expiratory pressure, flutter link device) is ineffective, not tolerated, or contraindicated.

III. Limitations/Exclusions

Individuals with a contraindication for external manipulation of the thorax as defined by the American Association of Respiratory Care (AARC) are excluded from use of the bronchial drainage system vest. These contraindications include:

A. Bronchospasms
B. Complaint of chest wall pain
C. Unstable head and/or neck injury
D. Subcutaneous emphysema
E. Recent epidural spinal infusion or spinal anesthesia
F. Recent skin grafts, or flaps, on the thorax
G. Burns, open wounds and skin infections of the thorax
H. Recently placed transvenous pacemaker or subcutaneous pacemaker
I. Osteomyelitis of the ribs
J. Active hemorrhage with hemodynamic instability
K. Suspected pulmonary tuberculosis
L. Lung contusion

IV. Administrative Guidelines

A. Precertification is required. To precertify, please complete HMSA's Precertification Request and mail for fax the form as indicated. Requests must include the following documentation from the medical record:
   1. For chronic diffuse bronchiectasis, high resolution or spiral CT confirming diagnosis and documentation supporting that patient has daily productive cough for at least six continuous months or more that two exacerbations per year requiring antibiotic therapy.
   2. More than one hospitalization in the past two years.
   3. Recent pulmonary function study results.
   4. Alternative therapy is ineffective, not tolerated or contraindicated or the caregiver is unable to provide effective chest therapy.
B. Authorizations will be given for a rental period of two months. After the two month rental period, the device may be considered for purchase. The physician must submit documentation from the medical record that the patient is compliant with the use of The Vest.

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<th>HCPCS</th>
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<td>E0483</td>
<td>High-frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
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V. Scientific Background

A literature search included a number of small, randomized studies that compared different mucus clearance techniques, typically in crossover studies. Pulmonary function and weight of expectorated sputum are typically analyzed immediately after treatment. Thus, these small short-term studies focus on intermediate outcomes, and do not include any data regarding long-term stabilization or improvement of lung function or a decrease in pulmonary exacerbations resulting in hospitalization.

Arens and colleagues prospectively studied 50 patients with cystic fibrosis admitted for acute pulmonary exacerbation to randomly receive either conventional physiotherapy or high-frequency chest compression three times a day. Both groups showed significant improvements in clinical status and pulmonary function tests were observed after seven and 14 days of treatment. Both
methods were found to be equally safe and effective in acute pulmonary exacerbations in cystic fibrosis patients.

Braggion and colleagues conducted a study of 16 hospitalized patients with cystic fibrosis to compare short-term efficacy of three different chest physiotherapy (CPT) regimens: postural drainage, positive expiratory pressure physiotherapy and high-frequency chest compression physiotherapy. The three CPT regimens and a control treatment (CONT) were administered in a random sequence, each patient receiving each treatment twice a day (in 50 minute sessions) for two consecutive days. Wet and dry weights of sputum collected during the sessions were greater for all CPT regimens than for CONT. No significant differences between the three CPT regimens for both wet and dry weights were found when the number of coughs was taken into account.

Kluft and colleagues in a crossover trial, compared chest physical therapy and postural drainage (CPT/PD) to high-frequency chest wall oscillation (HFCWO) in stable cystic fibrosis patients. Twenty-nine patients were randomly assigned to alternate CPT/PD and HFCWO, on a daily basis, over a four-day period. Each patient received two days of each form of therapy; treatment frequency and length of treatment were the same for both techniques. Significantly more sputum was expectorated during HFCWO than during CPT/PD as determined by both wet and dry measurements.

Oermann and colleagues conducted a pilot study of 24 patients with cystic fibrosis who were randomly assigned to receive either The Vest ä Airway Clearance System or the Flutter device for four weeks followed by crossover to the other group. Spirometry, lung volume measures, quality of life and patient satisfaction were measured after each four-week treatment period. The only significant difference between the two groups was patient satisfaction; 50 percent of the participants preferred The Vest ä Airway Clearance System, while 37 percent preferred the flutter device.

Varekojis and colleagues compared high-frequency chest wall compression using The Vest and intrapulmonary percussive ventilation using the Percussionaire device to percussion and postural drainage (P/PD) in 24 hospitalized patients with cystic fibrosis. Patients used each modality for two days in a randomized order over a six-day period. While wet sputum weights from use of the Percussionaire device were significantly greater than The Vest™, there was no significant difference in any of the modalities in dry sputum weights. In addition, patients found use of each of the devices to be equally acceptable when questioned about comfort, convenience, effectiveness and ease of use.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.
Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References