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 air flow 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 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
   A. The Vest™ is covered when all of the following criteria are met (subject to the Limitations/Exclusions and Administrative Guidelines):
      1. The device must be recommended by a pulmonologist.
      2. 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.
      3. The patient has been hospitalized more than once for pulmonary related conditions within the past two years.
      4. 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.
      5. Caregiver is unable to provide effective chest percussion and postural drainage.
      6. Alternative therapy (e.g., daily percussion and postural drainage, autologous drainage, positive end expiratory pressure, flutter link device) is ineffective, not tolerated, or contraindicated.

   B. The use of a high frequency chest wall oscillation device beyond the first two months of therapy is covered when documentation supports that the patient is compliant with therapy and benefiting from therapy.

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 for an initial two month rental. 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. Precertification is required for continued capped rental of a high frequency chest wall oscillation device beyond the initial two month rental period. Documentation from the medical record supporting that the patient is compliant with and benefiting from the use of the device must be submitted.

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0483</td>
<td>High-frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
</tr>
<tr>
<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each</td>
</tr>
<tr>
<td>A7026</td>
<td>High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each</td>
</tr>
</tbody>
</table>

V. Scientific Background  
Cystic Fibrosis  
In 2009, a Cochrane review was published that evaluated the evidence on oscillating devices for the treatment of cystic fibrosis. Investigators identified 30 randomized controlled trials (RCTs) with 708 patients that compared oscillatory devices to another recognized airway clearance technique. Eleven studies used a parallel design and 19 were crossover studies. Ten of the included studies were published as abstracts only. The majority, 16, were conducted in the United States. Sample sizes of individual studies ranged from 5 to 166, with a median of 20 participants. There were 16
studies using the Flutter device as a comparison, 11 using high-frequency chest wall oscillation, 5 using intrapulmonary percussive ventilation, and 2 using Cornet. No studies were identified that compared Acapella to another treatment. Study duration ranged from 1 week to 1 year; 21 of the studies were of less than 3 months’ duration and 10 lasted less than 1 week. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and quality-of-life measures. Findings of the studies could not be pooled due to the variety of devices used, outcome measures and lengths of follow-up. The authors concluded that there is a lack of evidence supporting any one airway clearance technique or device over another and that there is a need for adequately powered randomized controlled studies with long-term follow-up.

Findings from selected randomized controlled trials included in the Cochrane review are described below:

Oermann and colleagues conducted a pilot study of 24 patients with cystic fibrosis who were randomly assigned to receive either the Vest Airway Clearance System or the Flutter device for 4 weeks followed by crossover to the other group. Spirometry, lung volume measures, quality of life, and patient satisfaction were measured after each 4-week treatment period. The only significant difference between the groups was patient satisfaction; 50% of the participants preferred the Vest Airway Clearance System, while 37% preferred the Flutter device.

App and colleagues performed a randomized trial with a crossover design comparing the Flutter device and autogenic drainage in 14 patients with cystic fibrosis. Patients received therapy with either autogenic drainage or the Flutter device and then crossed over to the alternate treatment. At the beginning and end of each 4-week interval, pulmonary function was measured before and after an acute 30-minute therapy. At the end of the session, the weight and viscoelasticity of the sputum were evaluated. No significant changes in pulmonary function or sputum volume were noted throughout the study. Sputum viscoelasticity was lower in those receiving Flutter therapy, potentially allowing it to be cleared more easily by cough and airflow mechanisms.

Newhouse and colleagues reported on the results of a randomized trial with crossover design that compared the results of the Percussionaire device and the Flutter device in 8 patients with cystic fibrosis. Each regimen was randomly administered to each patient on 3 separate days during 3 successive weeks. Post-treatment pulmonary function tests were obtained at 1 and 4 hours after each treatment regimen. The weight of sputum samples collected over 4 hours after treatment was also recorded. There was no difference in sputum quantity with any method studied. Results of pulmonary function tests were inconsistent in this small trial.

In a randomized trial, McIlwaine and colleagues compared positive expiratory pressure (PEP) and the Flutter device in 40 children with cystic fibrosis. Participants were randomly assigned to physiotherapy with PEP or the Flutter device for 1 year. Clinical status, pulmonary function, and compliance were measured at regular intervals throughout the year. In the PEP group the pulmonary function remained relatively stable, while in the Flutter group, there was a greater mean annual rate of decline in forced vital capacity. This difference did not become apparent until 6 to 9 months into the study, underlining the importance of long-term results.

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 2 days in a randomized order over a 6-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.

Several additional RCTs have been published since the 2009 Cochrane review. Similar to the earlier trials, these tended to be underpowered due to small sample sizes and/or high dropout rates and did not find clear advantages of one oscillatory device over another. Details on representative recent studies are as follows:

Pryor and colleagues evaluated patients aged 16 years and older with cystic fibrosis from a single center in the U.K. The 75 patients were randomly assigned to receive 1 of 5 treatments for 1 year (15 per group): the Cornet device, the Flutter device, PEP, active cycle of breathing technique or autogenic drainage. Sixty-five of 75 (87%) patients completed the study, and these were included in the analysis. Mean forced expiratory volume in one second (FEV1) values at 12 months, the primary outcome, were 1.90 +/- 0.89 in the Cornet group (n=14), 2.43 +/- 0.94 in the Flutter group (n=12), 2.02 +/- 1.17 in the PEP group (n=13), 1.94 +/- 0.80 in the active cycle of breathing group (n=13), and 2.64 +/- 1.22 in the autogenic drainage group (n=13). The difference among the 5 groups was not statistically significant for FEV1 or any other lung function variable; however, this study had a small number of patients per group.

Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis. Patients were assigned to receive treatment with P/PD (n=58), the Flutter device (n=51), or the Vest (n=57). Investigators planned to evaluate participants on a quarterly basis for 3 years. However, dropout rates were high and consequently the trial ended early; 35 (60%), 16 (31%), and 5 (9%) patients withdrew from the postural drainage, Flutter, and Vest groups, respectively. Fifteen patients withdrew in the first 60 days (11 of these on the day of randomization) and the remainder after 60 days. The most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13), and lack of time (n=7). At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat (ITT) analysis found no significant differences between treatment groups in the modeled rate of decline for FEV1 predicted or forced vital capacity (FVC, %) predicted. The small sample size and high dropout rate greatly limit the conclusions that might be drawn from this study.

Bronchiectasis

Several small RCTs were identified that included patients with bronchiectasis. Thompson and colleagues compared the Flutter device to the active cycle of breathing technique in 17 patients. There were no significant between-group differences in outcomes e.g., peak expiratory flow rate, spirometric tests, and quality of life. In a 2007 cross-over study with 36 patients, Eaton and colleagues compared the Flutter device, the active cycle of breathing technique and active cycle of breathing plus postural drainage, in random order. Total sputum weight was highest after active cycle of breathing plus postural drainage; patient preference was highest for use of the Flutter device. In a study of 20 patients with acute exacerbation of bronchiectasis during antibiotic therapy, Patterson et al. found no difference in changes in lung function with the “usual” airway clearance approach compared to Acapella.
Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 2 academic medical centers while this policy was under review in December 2008. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The reviewers indicated that the available studies demonstrate that these devices are comparable to chest physiotherapy for both cystic fibrosis and bronchiectasis. The clinical input was not supportive of using oscillatory devices for treatment of COPD.

Summary
Oscillatory devices are designed to move mucus and clear airways. In patients with cystic fibrosis, it is difficult to reach scientific conclusions regarding the relative efficacy of oscillatory therapies compared to standard treatment with daily percussion and postural drainage. However, findings from randomized controlled trials, combined with clinical input, suggest that oscillatory devices may be comparable to chest physical therapy for cystic fibrosis patients in some situations. The available evidence and clinical input also suggest that oscillatory devices may be appropriate for treating diffuse bronchiectasis in similar situations. Thus, these devices may be considered medically necessary when chest physical therapy has failed or is unavailable or not tolerated by the patient. The sparse data do not suggest that any one oscillatory device is superior to another for cystic fibrosis or bronchiectasis. The Flutter® device, autogenic drainage, and positive expiratory pressure are simple devices or maneuvers that can be learned by most patients. In contrast, intrapulmonary percussive ventilation or high-frequency chest wall compression, e.g., with the Vest™ Airway Clearance System are more complex devices. The use of high-frequency chest wall compression and intrapulmonary percussive ventilation devices in other chronic pulmonary diseases, such as COPD, is considered investigational due to insufficient evidence on the impact of treatment on health outcomes.

Practice Guidelines and Position Statements
The 2006 guidelines from the American College of Chest Physicians recommend (level of evidence; low) that in patients with cystic fibrosis, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physiotherapy.
In April 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. They recommend airway clearance therapies for all patients with cystic fibrosis but state that no therapy has been demonstrated to be superior to others (level of evidence, fair; net benefit, moderate; grade of recommendation, B). They also issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized based on factors such as age and patient preference.
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