High Frequency Chest Wall Oscillation Devices

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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. In patients with CF, it is difficult to reach scientific conclusions regarding the relative efficacy of oscillatory therapies compared with standard treatment with daily percussion and postural drainage. However, findings from randomized controlled trials (RCTs), combined with clinical input, suggest that oscillatory devices may be comparable with chest physical therapy for CF 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.

A 2013 RCT, conducted with CF patients, found better outcomes with positive expiratory pressure (PEP) than high-frequency chest wall oscillation, but other evidence on the relative efficacy of devices is limited. The Flutter® device, autogenic drainage, and PEP 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.

II. Criteria/Guidelines
A. The Vest is covered when all of the following criteria are met (subject to the Limitations 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

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>
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<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>
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V. Scientific Background

A number of randomized controlled trials (RCTs) and a Cochrane systematic review of RCTs have evaluated oscillatory devices for the treating patients with cystic fibrosis. The Cochrane review was published in 2009. Investigators identified 30 RCTs with a total of 708 patients that compared oscillatory devices with 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. Most, 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 with 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 RCTs with long-term follow-up.

In 2013, McIlwaine et al published an RCT comparing 2 types of oscillatory devices. The study differed from previous trials in several ways. It had a larger sample size (n=107) and the primary outcome measure was a clinically meaningful outcome, i.e., number of pulmonary exacerbations requiring an antibiotic. Moreover, the study was conducted over a relatively long time period (1 year), was multicenter, and was not industry-funded, although industry did donate devices.

The study included individuals older than 6 years of age with clinically stable cystic fibrosis; age ranged from 6 to 47 years. Patients were randomized to perform either positive expiratory pressure (PEP) using a face mask (n=51) or high-frequency chest wall oscillation (HFCWO) using the inCourage system (n=56) for 1 year. After randomization, there was a 2-month washout period.
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(w/o knowledge of treatment group assignment). Eight patients in each arm dropped out after randomization and before treatment, and another 3 patients dropped out during the intervention phase. A total of 88 of 107 (82%) randomized patients completed the study. By the end of 1 year, there were 49 exacerbations requiring antibiotics in the PEP group and 96 in the HFCWO group; the difference between groups was statistically significant, favoring PEP ($p=0.007$). The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group ($p=0.02$). There was not a statistically significant difference in pulmonary measures, including FEV1. Limitations of this study were that patients were not blinded, and there was nearly a 20% dropout rate.

Findings from other representative RCTs follow (this includes studies from the Cochrane review, as well as more recent studies):

In 2010, Sontag et al conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis. Patients were assigned to receive treatment with percussion and postural drainage (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.

Pryor et al (2010) 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 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.

Section Summary
A number of RCTs and systematic reviews have tended to find that oscillatory devices are at least as effective as chest physical therapy for treatment of cystic fibrosis. There is limited evidence that 1 device is superior to another, although a 2013 RCT found better outcomes with PEP than HFCWO.

Bronchiectasis
In 2013, Lee et al published a Cochrane review on airway clearance techniques for treating bronchiectasis. Five small RCTs comparing airway clearance techniques with sham or an
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alternative treatment were identified. Sample sizes ranged from 8 to 20 patients, and the 5 studies included a total of 51 patients. Three of the 5 trials used the Flutter device and all were unblinded. The investigators did not pool study findings. Only 1 trial, a crossover study with 20 patients, reported primary outcomes of interest to Cochrane investigators; exacerbations and quality of life. This study, published by Murray et al, did not find a statistically significant difference at 12 weeks in the number of exacerbations; there were 5 exacerbations with the Acapella device and 7 without the Acapella device (p=0.48). There was significantly better cough-related quality of life after 12 weeks of airway clearance compared with no airway clearance.

Also in 2013, Nicolini et al published an RCT evaluating HFCWO using the Vest Airway Clearance System in patients with bronchiectasis. Participants were randomized to 1 of 3 groups: HFCWO (n=10), chest physical therapy (n=10), or medical therapy without airway clearance (n=10). Patients were treated 5 days a week for 15 days. The primary outcome measures included the Breathlessness, Cough and Sputum Scale (BCSS), the COPD Assessment Test (CAT), and the Modified Medical Research Council (MMRC) Dyspnea Scale. On all of these measures, the HFCWO and chest physical therapy groups showed significantly greater improvement compared with the medical treatment-only group (p=0.001 for each comparison). In addition, improvement on the BCSS and CAT scales, but not the MMRC scale was significantly better in the HFCWO group compared with the chest physical therapy group.

Section Summary

A 2013 systematic review identified only 5 small RCTs evaluating oscillatory devices for treating bronchiectasis and most of these did not report clinically important outcomes. Another small RCT, not included in the systematic review, found better outcomes with HFCWO or chest physical therapy compared to medical treatment alone. In this study, HFCWO was at least as good as chest physical therapy, and as superior to chest physical therapy on some outcome measures.

Chronic Obstructive Pulmonary Disorder

At least 2 systematic reviews of studies on airway clearance techniques in patients with chronic obstructive pulmonary disorder (COPD) have been published. Both reviews addressed a variety of techniques i.e., they were not limited to studies on oscillatory devices. The 2011 review by Ides et al identified 6 studies evaluating PEP in COPD patients, 4 of whom used oscillatory devices (Flutter or Cornet), and one 2007 study on high-frequency chest wall oscillation. Sample sizes in individual studies ranged from 10 to 50 patients; the study with the largest sample size was published in German. The Ides review did not pool study findings but the authors commented that the evidence on techniques such as oscillating PEP is poor due to a lack of appropriate trials. The 2012 Cochrane review on airway clearance techniques for COPD did not specifically discuss the number of studies or the results of studies on oscillatory devices.

More recent studies that have evaluated HFCWO in patients with COPD tended to find that HFCWO did not result in significant improvement in health outcomes. Chakrovorty et al in the United Kingdom published a randomized crossover study that included patients with moderate to severe COPD and mucus hypersecretion. Patients received HFCWO or conventional treatment, in random order, for 4 weeks, with a 2-week wash-out period between treatments. Thirty patients enrolled in the study and 22 (73%) completed the trial; 8 patients withdrew due to COPD exacerbations. The primary outcome was quality of life; this was measured with the St. George’s
Respiratory Questionnaire (SGRQ). Only 1 of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared with before treatment, with a decrease in the mean score from 72 to 64 (p=0.02). None of the 4 dimensions of the SGRQ improved after conventional treatment. There were no significant differences in secondary outcomes such as FEV1 or FVC after either treatment compared with before treatment. The study was limited by the relatively high dropout rate and lack of ITT analysis.

In 2013, Goktalay et al in Turkey published a study that included 50 patients with stage 3-4 COPD who were hospitalized for COPD exacerbations. Patients were randomized to receive 5 days of treatment with medical therapy plus HCFWO using the Vest Airway Clearance System (n=25) or medical therapy-only (n=25). At day 5, outcomes, including FEV1, scores on the MMRC dyspnea scale and the 6-minute walk test did not differ significantly between groups. This was a short-term study and included hospitalized patients who may not be similar to COPD patients treated on an outpatient basis.

Section Summary
There are limited studies evaluating oscillatory devices for the treatment of COPD, and the available evidence did not tend to find that these devices were more effective than conventional treatment.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
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.

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 with chest physical therapy for both cystic fibrosis and bronchiectasis. The clinical input was not supportive of using oscillatory devices for treatment of COPD.

Summary of Evidence
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 with standard treatment with daily percussion and postural drainage. However, findings from randomized controlled trials (RCTs), combined with clinical input, suggest that oscillatory devices may be comparable with 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. A 2013 RCT, conducted with cystic fibrosis patients, found better outcomes with positive expiratory pressure (PEP) than high-frequency chest wall oscillation, but
other evidence on the relative efficacy of devices is limited. The Flutter® device, autogenic drainage, and PEP 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 chronic obstructive pulmonary disorder, 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 physical therapy.

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.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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 Hawai‘i’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


