Kansas City

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

**Policy Number:** 1.01.15
**Origination:** 3/2001
**Last Review:** 3/2014
**Next Review:** 3/2015

## Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for oscillatory devices when it is determined to be medically necessary because the criteria shown below are met.

## When Policy Topic is covered

Use of oscillatory positive expiratory pressure (PEP) device- may be considered **medically necessary** in patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.

High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices may be considered **medically necessary** in patients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (see Considerations) including chest computed tomography scan) when standard chest physiotherapy has failed OR standard chest physiotherapy is unavailable or not tolerated. 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 patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physiotherapy and, if appropriate, use of an oscillatory positive expiratory pressure device), or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.

## When Policy Topic is not covered

High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered **not medically necessary** 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 situations other than those specified above.

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease (COPD), are considered **investigational.**

## Considerations

For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months or more than 2 times per year exacerbations requiring antibiotic therapy and confirmed by high resolution or spiral chest computed tomography scan.

For the chest wall compression devices, a trial period to determine patient and family compliance may be considered. Those who appear to benefit most from the compression devices are adolescents and adults due to lifestyle factors in which manual P/PD may essentially not be available.

A trial period may also be helpful because patients' responses to the various types of devices can be variable; the types of devices should be considered as alternative, and not equivalent, devices.

Oscillatory devices such as the FLUTTER® device, the Vest™ Airway Clearance System, and Percussionaire device have been primarily investigated as an alternative (not adjunct) to conventional chest physical therapy. Since the published clinical data do not suggest that these devices are associated with an increased health benefit, their use primarily represents a convenience to the patient, and it is on this basis that they are considered not medically necessary (unless conventional chest physical therapy has failed or is unavailable).

## Description of Procedure or Service

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).

### Background

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 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 patient 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 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) 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).

This policy addresses outpatient use of oscillatory devices. Inpatient device use e.g., in the immediate post-surgical period, is not included in the policy.

**Regulatory Status**
Several oscillatory devices have been cleared for marketing by the FDA through the 510(k) process including the following:

- The Bird IPV Noncontinuous Ventilator (Percussionaire Corp) in 1989.
- FLUTTER Mucus Clearance Device in 1994. The FLUTTER device is current marketed in the United States by Axcan.
- 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.
- The Acapella device (DHD Healthcare) in 1999.
- The RC Cornet Mucus Clearing Device (PARI Respiratory Equipment) in 1999.

## Rationale

This policy was originally created in 1997 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed from December 18, 2012 to December 20, 2013. Following is a summary of the literature to date:

### Cystic Fibrosis

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. (1) Investigators identified 30 randomized controlled trials (RCTs) with a total of 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.

Since publication of the Cochrane review, additional RCTs have been published. For the most part, these studies 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. Moreover, studies tended to report sputum weight or pulmonary function measures e.g. forced expiratory volume in one second (FEV1) as the primary outcome measure rather than functional outcomes such as exacerbation rates.

In 2013, McIlwaine and colleagues published an RCT comparing 2 types of oscillatory devices. (2) 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., the 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 over 6 years of age with clinically stable cystic fibrosis; age ranged from 6 to 47 years. Patients were randomized to perform either PEP using a face mask (n=51) or HFCWO using the inCourage system (n=56) for 1 year. After randomization, there was a 2 month washout period (without 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% drop-out rate.

Findings from other representative RCTs are described below (this includes studies from the Cochrane review as well as more recent studies):

Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis. (3) 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.

Pryor and colleagues evaluated patients aged 16 years and older with cystic fibrosis from a single center in the U.K. (4) 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.

McIlwaine and colleagues compared positive expiratory pressure (PEP) and the Flutter device in 40 children with cystic fibrosis. (5) 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. (6) 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.

Section summary: A number of RCTs and systematic reviews have tended to find that oscillatory devices are at least as effective as chest physiotherapy 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 and colleagues published a Cochrane review on airway clearance techniques for treating bronchiectasis. (7) Five small RCTs comparing airway clearance techniques to sham or an 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 and colleagues, 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). (8) There was significantly better cough-related quality of life after 12 weeks of airway clearance compared to no airway clearance.

Also in 2013, Nicolini and colleagues published an RCT evaluated HFCWO using the Vest Airway Clearance System in patients with bronchiectasis. (9) Participants were randomized to 1 of 3 groups: HFCWO (n=10), chest physiotherapy (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 three of these measures, the HFCWO and chest physiotherapy groups showed significantly greater improvement compared to the medical treatment-only group (p=0.001 for each comparison). In addition, improvement on the BCBSS and CAT scales, but not the MMRC scale was significantly better in the HFCWO group compared to the chest physiotherapy 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 physiotherapy compared to medical treatment alone. In this study, HFCWO was at least as good as chest physiotherapy, and as superior to chest physiotherapy on some outcome measures.

**Chronic Obstructive Pulmonary Disease (COPD)**

At least 2 systematic reviews of studies on airway clearance techniques in patients with COPD have been published. (10, 11) Both reviews addressed a variety of techniques i.e., they were not limited to studies on oscillatory devices. The 2011 review by Ides and colleagues identified 6 studies evaluating positive expiratory pressure in COPD patients, 4 of which used oscillatory devices (Flutter or Cornet), and 1 2007 study on high-frequency chest wall oscillation. (10) 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. (11)

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 and colleagues in the United Kingdom published a randomized cross-over study that included patients with moderate to severe COPD and mucus hypersecretion. (12) 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 out of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared to 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 to before treatment. The study was limited by the relatively high drop-out rate and lack of intention-to-treat analysis.

In 2013, Goktalay and colleagues in Turkey published a study that included 50 patients with stage 3-4 COPD who were hospitalized for COPD exacerbations. (13) 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**

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. A 2013 RCT, conducted with cystic fibrosis patients, found better outcomes with PEP than HFCWO, but other evidence on the relative efficacy of devices is limited. 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. (14)

In April 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. (15) 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**

No national coverage determination.

References


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14. McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. Chest 2006; 129(1 suppl):250S-59S.
15. Flume PA, Robinson KA, O'Sullivan BP et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respirat Care 2009; 54(4):522-37.


## Billing Coding/Physician Documentation Information

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| **94669** | Mechanical chest wall oscillation to facilitate lung function, per session |
| **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 |
| **E0481** | Intrapulmonary percussive ventilation system and related accessories |
| **E0483** | High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each |
| **E0484** | Oscillatory positive expiratory pressure device, nonelectric, any type, each |

**S8185** Flutter device

## Additional Policy Key Words

N/A

## Policy Implementation/Update Information

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| 3/1/01 | New policy. Added to DME section, considered medically necessary with criteria. |
| 3/1/02 | No policy statement changes. |
| 3/1/03 | No policy statement changes. |
| 6/1/04 | Policy statement revised to indicate devices are either not medically necessary or investigational depending on indication. However, special consideration may be given to individual patients meeting criteria. |
| 3/1/05 | No policy statement changes. |
| 3/1/06 | No policy statement changes. |
| 3/1/07 | Policy updated to remove individual consideration indications. The effective date of the change is 8/15/07. |
| 3/1/08 | No policy statement changes. |
| 12/11/08 | Interim Change. Policy statements changed to indicate high-frequency chest wall compression devices may be medically necessary in cystic fibrosis and chronic bronchiectasis when specific criteria are met and that flutter valves and Acapella device may be considered medically necessary in some cases of hypersecretory chronic lung diseases. Chest wall compression devices remain investigational for other conditions such as COPD. |
| 3/1/09 | No policy statement changes. |
| 3/1/10 | No policy statement changes. |
| 5/1/10 | Policy statements changed to indicate intrapulmonary percussive devices may be medically necessary in cystic fibrosis and chronic bronchiectasis when specific criteria are met. (Same as criteria for high-frequency chest wall compression devices). |
| 3/1/11 | No policy statement changes. |
| 3/1/12 | No policy statement changes. |
| 3/1/13 | No policy statement changes. |
| 3/1/14 | In first 2 medically necessary statements, Flutter valve or Acapella device changed to oscillatory positive expiratory pressure device. In second policy statement, “standard chest physiotherapy treatment” changed to “standard treatment”. Added cpt for 2014. |