Title: Oscillatory Devices for the Treatment of Cystic Fibrosis and other Respiratory Disorders

Professional
Original Effective Date: May 24, 2005
Revision Date(s): October 1, 2001; May 25, 2004; September 16, 2004; May 25, 2005; November 2, 2006; February 1, 2007; October 26, 2010; March 25, 2011; September 29, 2011; May 15, 2012; June 14, 2013; December 31, 2013
Current Effective Date: May 15, 2012

Institutional
Original Effective Date: November 29, 2010
Revision Date(s): March 25, 2011; September 29, 2011; May 15, 2012; June 14, 2013; December 31, 2013
Current Effective Date: May 15, 2012

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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 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).

**Regulatory Status**

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (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 currently 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.

POLICY
A. Use of the FLUTTER® valve or Acapella device may be considered medically necessary in patients with hypersecretory lung disease (i.e., produce excessive mucus):
   1. who have difficulty clearing the secretions; AND
   2. recurrent disease exacerbations

B. High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices may be considered medically necessary in patients with cystic fibrosis, chronic diffuse bronchiectasis, or cerebral palsy patients with lung disease and recurrent pulmonary infections when:
   1. standard chest physiotherapy has failed; OR
   2. standard chest physiotherapy is unavailable or not tolerated

C. 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, are considered experimental / investigational.

Policy Guidelines
1. 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.

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

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 for the period December 2011 through January 7, 2013. Following is a summary of the literature to date:
Cystic fibrosis
In 2009, a Cochrane review was published that evaluated the evidence on oscillating devices for the treatment of cystic fibrosis. (1) 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. (2) 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. (3) 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. (4) 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. (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.

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. (7) 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. (8) 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. (9) 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. (10) 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. (11)

Chronic Obstructive Pulmonary Disease (COPD)
At least 2 systematic reviews of studies on airway clearance techniques in patients with COPD have been published. (12, 13) 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 study on high-frequency chest wall oscillation. (12) 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. (13)

In 2011, Chakrovorty and colleagues in the United Kingdom published a randomized cross-over study evaluating use of high-frequency chest wall oscillation in patients with moderate to severe COPD and mucous hypersecretion. (14) 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.

Ongoing clinical trials
Long-term study, comparing Vest therapy to Positive Expiratory Pressure (PEP) therapy in the treatment of cystic fibrosis (NCT00817180): (15) This open-label RCT is comparing the safety and efficacy of high-frequency chest wall oscillation using the Vest System to PEP. The study includes patients age 6 years and older with cystic fibrosis, and estimated enrollment is 1,707 individuals. The primary outcome measure is the difference between groups in the number of respiratory exacerbations during 1 year. The study is being conducted in Canada and is sponsored by the University of British Columbia.
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.

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. (16)

In April 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. (17) 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.
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

**CPT/HCPCS**

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<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each</td>
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<td>A7026</td>
<td>High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each</td>
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<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and related accessories</td>
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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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<td>E0484</td>
<td>Oscillatory positive expiratory pressure device, nonelectric, any type, each</td>
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<td>S8185</td>
<td>Flutter device</td>
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**DIAGNOSIS**

These diagnoses are otherwise subject to medical policy as stated above

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<td>Cystic fibrosis; with pulmonary manifestations</td>
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<td>277.03</td>
<td>Cystic Fibrosis; with gastrointestinal manifestations</td>
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<tr>
<td>277.09</td>
<td>Cystic Fibrosis; with other manifestations</td>
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<td>494.0</td>
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<td>Bronchiectasis; with acute exacerbation</td>
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ICD-10 Diagnosis *(Effective October 1, 2014)*

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<td>J47.1</td>
<td>Bronchiectasis with (acute) exacerbation</td>
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**REVISIONS**

<table>
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| 10-26-2010 | Description section updated.  
In Policy section:
- Liberalized to the current policy language from:  
  "There is no clinical data to show oscillatory devices provide any additional health benefit compared to conventional chest physical therapy. However, conservative
therapy should be tried and failed (e.g. flutter valve) before an oscillatory device is considered medically necessary in cystic fibrosis patients who lack a caregiver to perform routine percussion and postural drainage (P/PD) or are intolerant of P/PD.

Other applications of oscillatory devices including their use as an adjunct to chest physical therapy or their use in diseases other than cystic fibrosis, such as bronchiectasis or COPD, are considered investigational."

Rationale section added.

In Coding section:
- Added HCPCS codes: E0481, E0484
- Added Diagnosis codes: 277.01, 277.03, 277.09, 494.0, 494.1

References section updated.

03-25-2011 Rationale section updated.
Reference section updated.

09-29-2011 Changed the policy title from “Chest Oscillation Vest” to “Oscillatory Devices for the Treatment of Cystic Fibrosis and other Respiratory Disorders.”

Added a Policy Guideline section.
Updated the Reference section.

05-15-2012 In the Policy section:
- In Item B, inserted "or cerebral palsy patients with lung disease and recurrent pulmonary infections" to read "High frequency chest wall compression devices and intrapulmonary percussive ventilation devices may be considered medically necessary in patients with cystic fibrosis, chronic diffuse bronchiectasis, or when cerebral palsy patients with lung disease and recurrent pulmonary infections, when:"

Rationale section updated.
Reference section updated.

06-14-2013 Rationale section updated.

In Coding section:
- Added ICD-10 Diagnosis (Effective October 1, 2014)

Reference section updated.

12-31-2013 In Coding section:
- Added CPT code 94669 (Effective January 1, 2014)

REFERENCES


Other References:

1. Blue Cross and Blue Shield of Kansas Internal Medicine Liaison Committee, August 30, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).

2. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, August 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).

3. Blue Cross and Blue Shield of Kansas Medical Advisory Committee meeting, November 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).

4. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, August 2011.

5. C&A Medical Consultant, Board Certified Pediatric Intensivist (181), 03/30/12.