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

Professional
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Institutional
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Revision Date(s): March 25, 2011; September 29, 2011; May 15, 2012; June 14, 2013; December 31, 2013; May 28, 2015; September 3, 2016; August 10, 2017
Current Effective Date: August 10, 2017

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<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With cystic fibrosis</td>
<td>• Oscillatory devices</td>
<td>• Standard chest physical therapy</td>
<td>• Symptoms</td>
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<td>• Medication use</td>
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**DESCRIPTION**

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage method of airway clearance for patients with cystic fibrosis (CF). 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 disease (COPD), and respiratory conditions associated with neuromuscular disorders.

**OBJECTIVE**

The objective of this policy is to evaluate whether oscillatory devices improve health outcomes in patients with cystic fibrosis and other respiratory disorders.

**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 (PEP) 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. For example, autogenic drainage and active cycle of breathing technique both involve a combination of...
breathing exercises performed by the patient. PEP therapy requires patients to exhale through a resistor to produce PEPs 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.

High-frequency chest wall oscillation (HFCWO) devices (eg, the Vest Airway Clearance System, ThAIRapy Bronchial Drainage System, SmartVest Airway Clearance 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 airpulse 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 these techniques can be used as alternatives to daily percussion and postural drainage in patients with CF. Daily percussion and postural drainage 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). In addition, they could benefit patients with neuromuscular disease who have impaired cough clearance.

This policy addresses outpatient use of oscillatory devices. Inpatient device use (eg, in the immediate postsurgical period) is not included herein.

REGULATORY STATUS

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, those listed in Table 1.

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
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<tbody>
<tr>
<td>Bird IPV® Noncontinuous Ventilator</td>
<td>Percussionaire Corp.</td>
<td>1989</td>
</tr>
<tr>
<td>Flutter® Mucus Clearance Device</td>
<td>Axcan Scandipharm (for marketing in the United States)</td>
<td>1994</td>
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<tr>
<td>ThAIRapy Bronchial Drainage System (Vest® Airway Clearance System)</td>
<td>Hill-Rom</td>
<td>1998</td>
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<tr>
<td>Acapella® device</td>
<td>DHD Healthcare</td>
<td>1999</td>
</tr>
<tr>
<td>RC Cornet™ Mucus Clearing Device</td>
<td>PARI Respiratory Equipment</td>
<td>1999</td>
</tr>
<tr>
<td>inCourage® System</td>
<td>RespirTech</td>
<td>2005</td>
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Table 1. Oscillatory Devices Cleared by the Food and Drug Administration
Device | Manufacturer | Clearance Date
---|---|---
AerobiKA oscillating PEP device | Trudell Medical | 2013
Vibralung Acoustical Percussor | Westmed | 2014

PEP: positive expiratory pressure.

Food and Drug Administration product codes: BYI, BYT.

**POLICY**

A. Use of an oscillatory positive expiratory pressure (PEP) device may be considered medically necessary in patients with hypersecretory lung disease (ie, produce excessive mucus):
1. who have difficulty clearing the secretions; AND
2. who have recurrent disease exacerbations.

B. High-frequency chest wall compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered medically necessary in patients with cystic fibrosis, chronic diffuse bronchiectasis, or cerebral palsy with lung disease and recurrent pulmonary infections as determined by specific criteria (see Policy Guidelines) (including chest computed tomography scan) when:
1. standard chest physiotherapy has failed; OR
2. 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, ie, the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physical therapy and, if appropriate, use of an oscillatory PEP device) or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.

C. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use in patients with cystic fibrosis, chronic diffuse bronchiectasis, or cerebral palsy other than as specified above, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease or respiratory conditions are considered experimental / investigational.

**Policy Guidelines**

1. For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months or exacerbations more than 2 times per year requiring antibiotic therapy and confirmed by high-resolution or spiral chest CT scan.
2. 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 for whom, due to lifestyle factors, manual percussion and postural drainage (P/PD) may not be available.

3. 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.

**RATIONALE**

Literature was reviewed through April 25, 2017. Following is a summary of the key literature.

**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 (CF). The Cochrane review was updated in 2014. Investigators identified 35 RCTs with a total of 1050 patients that compared oscillatory devices with another recognized airway clearance technique. Fifteen studies used a parallel design and 20 were crossover studies. Ten of the included studies were published as abstracts only. Sixteen were conducted in the United States, and 14 of these were single-center studies. Sample sizes of individual studies ranged from 5 to 166 and half of the studies included children. 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 followup. 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.

Representative recent RCTs follow.

In 2013, Mcllwaine 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, ie, 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 CF; 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 (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. Eighty-eight (82%) of 107 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 forced expiratory volume in 1 second (FEV₁). Limitations of this study were that
In 2010, Sontag et al published a multicenter randomized trial with 166 adults and children with CF. 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) percent 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 CF from a single center from 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 (87%) of 75 patients completed the study and were included in the analysis. Mean (SD) 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: Cystic Fibrosis**

A number of RCTs evaluating oscillatory devices have had mixed findings and limitations (eg, small sample sizes, large dropout rates). A systematic review identified 35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. The study findings were not pooled due to heterogeneity in study designs and outcome measures. The systematic review concluded that results from additional RCTs with adequate power and long-term follow-up would permit conclusions on the effect of oscillatory devices on outcomes for cystic fibrosis.

**Bronchiectasis**

In 2015, Lee et al published a Cochrane review on airway clearance techniques for treating bronchiectasis. Seven RCTs comparing airway clearance techniques with sham or an alternative treatment were identified. Sample sizes ranged from 8 to 37 patients. All studies, except 1 (N=37), were crossover trials. Five trials used a PEP device, 1 used HFCWO, and 1 used postural drainage. The investigators did not pool study findings due to heterogeneity among studies. Primary outcomes of interest to the Cochrane reviewers were exacerbations, hospitalizations for bronchiectasis, and quality of life (QOL). Only 1 trial, a crossover study with 20 patients, reported exacerbations. This trial, published by Murray et al (2009), did not find a statistically significant
difference at 12 weeks in the number of exacerbations (there were 5 exacerbations with the oscillating PEP device vs 7 without the oscillating PEP device; p=0.48). Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Three studies reported QOL outcomes. The Murray trial found significantly better health-related quality of life (HRQOL) with a PEP device compared with control. The study by Svenningsen et al did not. The third study, by Nicolini et al, used HFCWO and found significantly better HRQOL with the oscillatory device than with control. The Cochrane reviewers noted that the studies were not blinded and that patient-reported QOL measures may have been subject to bias.

Herrero-Cortina et al (2016) reported on a crossover RCT that included 31 patients with bronchiectasis and mean daily spontaneous sputum production of 15 mL or more. Patients received 3 week-long airway clearance interventions in random order, with a 7-day washout period between interventions. The interventions were temporary PEP, autogenic drainage, and slow expiration with the glottis opened in the lateral position. Treatment sessions occurred on 3 nonconsecutive days during the week. There were no significant differences among treatments in the mean sputum clearance during the 24-hour period after each intervention, cough severity (measured using the total Leicester Cough Questionnaire score), or in lung function measures (eg, FEV1). Sputum production during physical therapy sessions was significantly higher in the autogenic drainage and slow expiration with the glottis opened interventions compared with the temporary PEP intervention (p<0.02).

Section Summary: Bronchiectasis
A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 reported the clinically important outcomes exacerbations or hospitalizations. Only 3 reported on QOL and trial findings were mixed. A 2016 crossover RCT did not find a significant benefit of temporary PEP compared with other airway clearance techniques.

Chronic Obstructive Pulmonary Disease
At least 2 systematic reviews have evaluated studies of airway clearance techniques in patients with chronic obstructive pulmonary disease (COPD). Both reviews addressed various techniques (ie, 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 which used oscillatory devices (Flutter or Cornet), and one 2007 study of HFCWO. 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. Reviewers noted that the evidence on techniques such as oscillating PEP was poor due to a lack of appropriate trials. The 2012 Cochrane review of airway clearance techniques for COPD did not specifically discuss the number or the results of studies on oscillatory devices.

Several randomized studies, two of which used a crossover design, were published after the systematic reviews discussed above. Chakrovorty et al (2011) assessed 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 washout period between treatments. Thirty patients enrolled in the trial and 22 (73%) completed it; 8 patients withdrew due to COPD exacerbations. The primary outcome was QOL as measured using the St. George’s Respiratory Questionnaire (SGRQ). Only 1 of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCWO.
compared with baseline, with a decrease in mean score from 72 to 64 (p=0.02). None of the 4 SGRQ dimensions improved after conventional treatment. There were no significant pre- to posttreatment differences in secondary outcomes (eg, FEV₁, FVC).

Svenningsen et al (2016) published an unblinded, industry-funded, randomized crossover study comparing oscillatory PEP with usual care in 32 COPD patients aged 40 to 85 years. Each intervention period lasted 21 to 28 days. Five (16%) of 32 patients withdrew from the trial, leaving the remaining 27 patients for analysis. Findings were reported separately for the subgroup of sputum producers (n=14) and nonsputum producers (n=13) at baseline. In the nonsputum producers, there were not significant differences before and after PEP use in most outcomes, including FEV₁, FVC, FEV₁/FVC, 6-minute walk test (6MWT) distance, SGRQ total score, and Patient Evaluation Questionnaire (PEQ) total score. Scores differed significantly only on the PEQ ease of bringing up sputum subscale. In patients who were sputum producers at baseline, pre- versus post-PEP scores differed significantly for FVC, 6MWT distance, SGRQ total score, and the PEQ ease of bringing up sputum and patient global assessment subscales. There were no significant differences in FEV₁, FEV₁/FVC, or PEQ global score. The crossover studies had similar limitations including no between-group comparisons (ie, outcomes after oscillatory device use vs the control intervention), lack of ITT analysis, and short-term follow-up (immediate posttreatment period).

Goktalay et al (2013) reported on a parallel-group RCT evaluating HFCWO therapy, which included 50 patients with stage 3 or 4 COPD hospitalized for COPD exacerbations. Patients were randomized to 5 days of treatment with medical therapy plus HFCWO (n=25) or to medical therapy only (n=25). At day 5, outcomes including FEV₁, modified Medical Research Council dyspnea scale scores, and the 6MWT distance, did not differ significantly between groups. This short-term trial included hospitalized patients who might differ from COPD patients treated on an outpatient basis.

Section Summary: Chronic Obstructive Pulmonary Disease
Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tended to use ITT analysis and between-group comparisons. Moreover, the published studies had mixed findings and did not support the use of oscillatory devices in COPD patients.

Respiratory Conditions Related to Neuromuscular Disorders
Children
A 2014 Cochrane review of the nonpharmacologic management of respiratory morbidity in children with severe global developmental delay addressed airway clearance techniques. Reviewers included RCTs and nonrandomized comparative studies. They identified 3 studies on HFCWO (1 RCT, 2 pre-post) and one on PEP (pre-post), with sample sizes from 15 and 28 patients.

The RCT by Yuan et al (2010) compared HCFWO to standard chest physical therapy in 28 patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic. Both groups were instructed to perform the assigned treatment for 12 minutes 3 times a day for the study period (mean, 5 months). Twenty-three (82%) of 28 patients completed the trial; all 5 dropouts were in the HCFWO group. The authors noted that the trial was exploratory and was not powered to detect statistically significant findings on of the primary outcomes (eg, incidence
and duration of acute respiratory infection requiring inpatient or patient antibiotics, treatment-related adverse events). There were no statistically significant differences between groups on primary outcomes. For example, 4 patients required inpatient intravenous antibiotics in the standard physical therapy group and none in the HCFWO group (p=0.09). Additionally, 7 patients required oral antibiotics in the standard physical therapy group and 3 in the HFCWO group (p=nonsignificant). No therapy-related adverse events were reported in either group. We did not identify any RCTs published after their Cochrane review on oscillatory devices in children with neuromuscular diseases.

Adults
Lange et al (2006) evaluated HFCWO in adults with amyotrophic lateral sclerosis (ALS). The trial included 46 patients with probable or definite ALS with respiratory conditions as evidenced by scores on the ALS Functional Rating Scale respiratory subscale between 6 and 11 (subscales range, 0 [complete ventilator support] to 12 [normal]). Patients were randomized to 12 weeks of HCFWO or to usual care. The primary end points were measures of pulmonary function after 12 weeks. Data were available for 35 (76%) of 46 patients at 12 weeks. There were no statistically significant between-group differences in pulmonary measures (FVC predicted, capnography, oxygen saturation, or peak expiratory flow). There was also no significant difference in the ALS Functional Rating Scale respiratory subscale score (worsening) at 12 weeks. Of symptoms assessed as secondary outcomes, there was significantly less breathlessness and night cough in the HCFWO group than in the usual care group, and groups did not differ significantly on other symptoms, including the noise of breathing, suction frequency, suction amount, day cough, and nocturnal symptoms.

Section Summary: Respiratory Conditions Related to Neuromuscular Disorders
We identified 2 RCTs and a systematic review evaluating oscillatory devices for treatment of respiratory conditions in neuromuscular disorders. One RCT was not powered to detect statistical significance. The other, conducted in ALS patients, did not find statistically significant improvement after HCFWO compared with usual care for the primary outcomes (pulmonary function measures) or for most secondary outcomes.

SUMMARY OF EVIDENCE
For individuals who have cystic fibrosis (CF) who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. A systematic review identified 35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. Study findings could not be pooled due to heterogeneity in study design and outcome measures. The systematic review concluded that additional RCTs are needed that are adequately powered and have long-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have bronchiectasis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 RCT reported the clinically important outcomes of exacerbations or
hospitalizations. Only 3 RCTs reported on quality of life, and findings were mixed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic obstructive pulmonary disease (COPD) who receive oscillatory devices, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tend to have small sample sizes, short follow-up periods, and limitations in their analyses (eg, lack of intention to treat analysis and between-group comparisons). Moreover, the published studies have mixed findings and do not clearly support the use of oscillatory devices in COPD patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have respiratory conditions related to neuromuscular disorders who receive oscillatory devices, the evidence includes 2 RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. One of the RCTs was not powered to detect statistical significance. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvement after high-frequency chest wall compression devices versus usual care in primary outcomes, in pulmonary function measures, or in most secondary outcomes.

CLINICAL INPUT RECEIVED FROM 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 2008. The reviewers indicated that the available studies demonstrated that these devices are comparable with chest physical therapy for CF and bronchiectasis. The most commonly mentioned clinical criteria were patients who failed or were intolerant of other methods of mucus clearance and patients who lacked caregivers to provide chest physical therapy. The clinical input did not support using oscillatory devices for treatment of COPD.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Chest Physicians
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.18

Cystic Fibrosis Foundation
In 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence.19 The Foundation recommended airway clearance therapies for all patients with cystic fibrosis, but stated that no therapy had been demonstrated to be superior to others (level of evidence: fair; net benefit: moderate; grade of recommendation: B).
U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<td>NCT03013452</td>
<td>Oscillating PEP vs Autogenic Drainage in People With Bronchiectasis (oPEP-vs-AD)</td>
<td>50</td>
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NCT: national clinical trial.

CODING

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

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

ICD-9 Diagnoses

These diagnoses are otherwise subject to medical policy as stated above

277.00  Cystic Fibrosis; without mention of meconium ileus
277.01  Cystic Fibrosis; with meconium ileus
277.02  Cystic fibrosis; with pulmonary manifestations
277.03  Cystic Fibrosis; with gastrointestinal manifestations
277.09  Cystic Fibrosis; with other manifestations
494.0   Bronchiectasis; without acute exacerbation
494.1   Bronchiectasis; with acute exacerbation

ICD-10 Diagnoses (Effective October 1, 2015)

E84.11  Meconium ileus in cystic fibrosis
E84.0   Cystic fibrosis with pulmonary manifestations
E84.19  Cystic fibrosis with other intestinal manifestations
### E84.8 Cystic fibrosis with other manifestations

### E84.9 Cystic fibrosis, unspecified

### J47.9 Bronchiectasis, uncomplicated

### J47.0 Bronchiectasis with acute lower respiratory infection

### J47.1 Bronchiectasis with (acute) exacerbation

### REVISIONS

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<td>- Liberalized to the current policy language from:</td>
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<td>&quot;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.&quot;</td>
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<td>- In Item B, inserted &quot;or cerebral palsy patients with lung disease and recurrent pulmonary infections&quot; to read &quot;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:&quot;</td>
</tr>
<tr>
<td></td>
<td>In Rationale section updated.</td>
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<tr>
<td></td>
<td>Reference section updated.</td>
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<tr>
<td>06-14-2013</td>
<td>Rationale section updated.</td>
</tr>
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<td></td>
<td>In Coding section:</td>
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<td></td>
<td>- Added ICD-10 Diagnosis (Effective October 1, 2014)</td>
</tr>
<tr>
<td></td>
<td>Reference section updated.</td>
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<tr>
<td>12-31-2013</td>
<td>In Coding section:</td>
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<td></td>
<td>- Added CPT code 94669 (Effective January 1, 2014)</td>
</tr>
<tr>
<td>05-28-2015</td>
<td>Updated Description section.</td>
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<td>In Policy section:</td>
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<td></td>
<td>- In Item A, removed “the FLUTTER® valve or Acapella” and added “an oscillatory positive expiratory pressure” to read, &quot;Use of an oscillatory positive expiratory pressure device may be considered medically necessary in patients with hypersecretory lung disease (i.e., produce excessive mucus):&quot;</td>
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Contains Public Information
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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>09-03-2016</td>
<td>Updated Rationale section.</td>
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<tr>
<td>09-03-2016</td>
<td>Updated References section.</td>
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**In Policy section:**
- Changed previous Item C to Item D.
- Added new Item C, "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, chronic bronchiectasis, or cerebral palsy in any other clinical situations; there are no clinical data to show that these devices provide any additional health benefit compared with conventional chest physical therapy in situations other than those specified here."
- In Policy Guidelines, added "1. 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 CT scan." 
- In Item 2, defined P/PD.
- Updated Rationale section.
- Updated References section.

<table>
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<tbody>
<tr>
<td>08-10-2017</td>
<td>Updated Description section.</td>
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**In Policy section:**
- Removed previous Item C, "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, chronic bronchiectasis, or cerebral palsy in any other clinical situations; there are no clinical data to show that these devices provide any additional health benefit compared with conventional chest physical therapy in situations other than those specified here."
- In new Item C (previous Item D), added "their use in patients with cystic fibrosis, chronic diffuse bronchiectasis, or cerebral palsy other than as specified above," and "or respiratory conditions" to read, "Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use in patients with cystic fibrosis, chronic diffuse bronchiectasis, or cerebral palsy other than as specified above, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease or respiratory conditions are considered experimental / investigational." 
- Updated Rationale section.
- Updated References section.
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); August 2013.
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, July 2011; July 2013.
5. C&A Medical Consultant, Board Certified Pediatric Intensivist (181), 03/30/12.