Policy Statement

Use of an oscillatory positive expiratory pressure (PEP) device (e.g., Flutter® or Acapella® 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 (HFCW) compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered medically necessary in patients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (see Policy Guidelines section) (including chest computed tomography [CT] scan) when either of the following occurs:

- Standard chest physical therapy has failed
- Standard chest physical therapy is unavailable or not tolerated

*Note: In considering the chest wall compression and intrapulmonary percussive ventilation (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 physical therapy and, if appropriate, use of an oscillatory positive expiratory pressure (PEP) device] or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it).

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, are considered investigational, including, but not limited to, their use for any of the following:

- In patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above
- As an adjunct to chest physical therapy
- In other lung diseases such as chronic obstructive pulmonary disease (COPD)
- Respiratory conditions associated with neuromuscular disorders

Policy Guidelines

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

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

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:

- Oscillatory Positive Expiratory Pressure (Active Devices):
  - Acapella® Vibratory PEP Therapy System (DHD Healthcare, Wampsville, NY) in 1999
  - AerobiKA (Trudell Medical, London, ON) in 2013
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

- Flutter® Mucus Clearance Device (Axcan Scandipharm Inc., Birmingham, AL) in 1994
- RC Comet™ Mucus Clearing Device (PARI Respiratory Equipment, Inc., Midlothian, VA) in 1999

- High-Frequency Chest Wall Compression (Passive Devices):
  - inCourage® System (Respiratory Technologies, Lakeville, MN) in 2005
  - The Vest™ Airway Clearance System (Hill-Rom Services, Inc., St. Paul, MN) - formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by FDA—most recently a fifth generation device.

- Intrapulmonary Percussive Ventilation
  - Bird IPV® Noncontinuous Ventilator (Percussionaire Corp., Sagle ID) in 1989
  - Vibralung Acoustical Percussor (Westmed Inc., Tucson AZ) in May 2014

Oscillatory devices such as the Flutter® device, the Vest™ Airway Clearance System, and Percussionaire IPV® device have been primarily investigated as an alternative (not adjunct) to conventional chest physical therapy. Because 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**

Oscillatory devices are alternatives to the standard daily percussion and postural drainage 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. Respiratory therapies and other providers may also use oscillatory devices are also proposed for other respiratory conditions such as diffuse bronchiectasis, chronic obstructive pulmonary disease, and respiratory conditions associated with neuromuscular disorders.

**Related Policies**

- N/A

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>ThAIRapy Bronchial Drainage System (Vest™ Airway Clearance System)</td>
<td>Hill-Rom</td>
<td>1998</td>
</tr>
<tr>
<td>Acapella® device</td>
<td>DHD Healthcare</td>
<td>1999</td>
</tr>
<tr>
<td>RC Comet™ Mucus Clearance Device</td>
<td>PARI Respiratory Equipment</td>
<td>1999</td>
</tr>
<tr>
<td>inCourage® System</td>
<td>RespirTech</td>
<td>2005</td>
</tr>
<tr>
<td>AerobiKA oscillating PEP device</td>
<td>Tuudell Medical</td>
<td>2013</td>
</tr>
<tr>
<td>Vibralung Acoustical Percussor</td>
<td>Westmed</td>
<td>2014</td>
</tr>
</tbody>
</table>

PEP: positive expiratory pressure.

Food and Drug Administration product codes: BYI, BYT.

### Rationale

#### Background
Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require the active participation of patients. They include oscillating positive expiratory pressure devices, such as Flutter and Acapella, in which the patient exhales multiple times through a device. The Flutter device is a small pipe-shaped, easily portable handheld device, with a mouthpiece at one end. It contains a high-density stainless steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs, resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create airflow oscillation.

Other airway clearance techniques also require active patient participation. For example, autogenic drainage and an active cycle breathing technique both involve a combination of breathing exercises performed by the patient. 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.

High-frequency chest wall oscillation devices (e.g., 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 patient participation. 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 inflate and deflate the vest against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

The Percussionaire device is another type of passive oscillatory device; it delivers intrapulmonary percussive ventilation. This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

All of these techniques may be alternatives to daily percussion and postural drainage in patients with cystic fibrosis, also known as chest physical therapy. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, often a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who 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 disease. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

This evidence review addresses the outpatient use of oscillatory devices. We do not address inpatient device use (e.g., in the immediate postsurgical period) here.

**Literature Review**

The most recent literature review was performed through April 25, 2017. Following is a summary of the key literature to date.

**Cystic Fibrosis**

A number of randomized controlled trials (RCTs) and a Cochrane systematic review of RCTs have evaluated oscillatory devices for treating patients with cystic fibrosis (CF). The Cochrane review addressed a variety of oscillatory devices and was last updated in 2014.1 Reviewers identified 35 RCTs (total N=1050 patients) that compared oscillatory devices with another recognized airway clearance technique. Fifteen studies used parallel design and 20 used crossover. Ten studies included were published only as abstracts. Sixteen were conducted in the United States, and 14 of them were single-center studies. Sample sizes of individual studies ranged from 5 to 166 patients, and half the studies included children. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and quality of life (QOL) measures. The overall risk of bias was unclear in about 85% of studies. Data could not be pooled due to the variety of devices, outcome measures, and lengths of follow-up used. Reviewers concluded that there was a lack of evidence supporting any specific 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.

Mcllwaine et al (2013) published an RCT comparing 2 types of oscillatory devices high-frequency chest wall oscillation (HFCWO) with positive expiratory pressure (PEP) mask therapy.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 trial was conducted over a relatively long period (1 year), was multicenter, and was not industry-funded, although the manufacturer donated devices. The trial included individuals older than 6 years of age with clinically stable CF; ages ranged from 6 to 47 years. Patients were randomized to perform PEP using a face mask (n=51) or HFCWO (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 but before treatment, and another 3 patients dropped out during the intervention phase. Eighty-eight (82%) of 107 randomized patients completed the trial. 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 no statistically significant difference in pulmonary measures, including forced expiratory volume in 1 second (FEV1). Limitations of this trial were a lack of patient blinding and a nearly 20% dropout rate. The trial was also stopped early without enrolling the expected number of patients and, thus, may have been underpowered to detect clinically significant differences between groups.

Sontag et al (2010) published a multicenter RCT enrolling 166 adults and children with CF, which compared outcomes for patients treated with postural drainage, the Flutter device, and HFCWO.3 Patients were assigned to receive treatment with percussion and postural drainage (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,
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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 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 limited the conclusions that can be drawn from this trial.

Pryor et al (2010) evaluated 75 patients ages 16 years and older with CF from a single center in the U.K.4 Patients were randomized to 1 of 5 treatments for 1 year (15 per group): the Comet device, the Flutter device, PEP, active cycle of breathing technique, or autogenic drainage. Sixty-five (87%) of 75 patients completed the trial and were included in the analysis. Mean (standard deviation) FEV1 values at 12 months (the primary outcome) were 1.90 liters (0.89) in the Comet group (n=14), 2.43 liters (0.94) in the Flutter group (n=12), 2.02 liters (1.17) in the PEP group (n=13), 1.94 liters (0.80) in the active cycle of breathing group (n=13), and 2.64 liters (1.22) in the autogenic drainage group (n=13). The differences between the 5 groups were not statistically significant for FEV1 or any other lung function variable; however, this trial 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 (e.g., small sample sizes, large dropout rates). A systematic review identified 35 RCTs comparing oscillatory devices with another recognized airway clearance technique; 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

Lee et al (2015) published a Cochrane review of airway clearance techniques for treating bronchiectasis.5 Reviewers identified 7 RCTs (total N=107 patients) comparing airway clearance techniques with sham or an alternative treatment. Sample sizes ranged from 8 to 37 patients. All studies were crossover trials, except one (N=37). Five trials used a PEP device, one used HFCWO, and one used postural drainage. Reviewers did not pool study findings due to heterogeneity among studies. Primary outcomes of interest to reviewers were exacerbations, hospitalizations for bronchiectasis, and QOL. Only 1 trial, a crossover study with 20 patients, reported exacerbations. Published by Murray et al (2009), this trial 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).6 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 QOL with a PEP device compared with control. The preliminary reporting of the study by Svenningsen et al (2013) did not.7 The third study (by Nicolini et al, 2013) used HFCWO and found significantly better health-related QOL with the oscillatory device than with control.8 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.9 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 (e.g., 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 assessing several types of oscillatory devices; only one reported the clinically important outcomes exacerbations or hospitalizations. Three 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 (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 which used oscillatory devices (Flutter or Comet), 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. Chakroverty 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 (e.g., 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 non-sputum producers (n=13) at baseline. In the non-sputum 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 (i.e., 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.
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 any of the primary outcomes (e.g., incidence and duration of acute respiratory infection requiring inpatient or outpatient 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 (subscale 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 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. The 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 technique; some were published only as abstracts. The review authors could not pool findings due to heterogeneity in study designs and outcome measures, and they concluded that additional adequately powered RCTs with long-term follow-up are needed to make conclusions about oscillatory devices for cystic fibrosis. 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 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 (e.g., 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input 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 from Blue Cross Blue Shield Association, input was received from two academic medical centers in 2008. Input indicated the available studies demonstrated that these oscillatory devices are comparable with chest physical therapy for cystic fibrosis 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. Clinical input did not support use of oscillatory devices for treatment of chronic obstructive pulmonary disease.

Practice Guidelines and Position Statements
American College of Chest Physicians
The 2006 guidelines from the American College of Chest Physicians recommended (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.18
Cystic Fibrosis Foundation

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

Medicare National Coverage

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

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<td>Ongoing</td>
<td>Oscillating PEP vs Autogenic Drainage in People With Bronchiectasis (oPEP-vs-AD)</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**
- History and physical and/or consultation notes including:
  - Previous treatment plan(s) and response(s)
  - Clinical findings and duration of daily productive cough and/or frequency of exacerbations of chronic diffuse bronchiectasis
  - Documentation of reasons why standard chest physical therapy cannot be performed, is unavailable, or is not tolerated
  - Documentation of frequent exacerbations of respiratory distress
- CT scan results to confirm chronic diffuse bronchiectasis

**Post Service**
- Results/reports of tests performed

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

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<thead>
<tr>
<th>Type</th>
<th>Code</th>
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<td>HCPCS</td>
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<td>High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each</td>
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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<th>Effective Date</th>
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<td>Administrative Review Administrative review of external experts by Policy Committee, accepted as New Policy</td>
<td>Medical Policy Committee</td>
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<td>Administrative Review with statement unchanged</td>
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<td>Policy Revision Indication updated - BCBSA MPP</td>
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<td>Medical Policy Committee</td>
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<tr>
<td>06/30/2015</td>
<td>Coding Update Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>08/01/2016</td>
<td>Policy title change from Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>08/01/2017</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
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**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance
with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.