Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

Policy Number: 1.01.15  Last Review: 3/2019

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

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

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

When Policy Topic is not covered
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 or chronic diffuse bronchiectasis other than as specified above, their use as an adjunct to chest physical therapy, and their use in other lung diseases such as chronic obstructive pulmonary disease or respiratory
conditions associated with neuromuscular disorders, are considered investigational.

**Considerations**

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

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

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

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

### Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Individuals:  
  • With cystic fibrosis | Interventions of interest are:  
  • Oscillatory devices  | Comparators of interest are:  
  • Standard chest physical therapy  | Relevant outcomes include:  
  • Symptoms  
  • Quality of life  
  • Hospitalizations  
  • Medication use |
| Individuals:  
  • With bronchiectasis | Interventions of interest are:  
  • Oscillatory devices  | Comparators of interest are:  
  • Standard chest physical therapy  | Relevant outcomes include:  
  • Symptoms  
  • Quality of life  
  • Hospitalizations  
  • Medication use |
| Individuals:  
  • With chronic obstructive pulmonary disease | Interventions of interest are:  
  • Oscillatory devices  | Comparators of interest are:  
  • Standard therapy  | Relevant outcomes include:  
  • Symptoms  
  • Quality of life  
  • Hospitalizations  
  • Medication use |
| Individuals:  
  • With respiratory conditions related to neuromuscular disorders | Interventions of interest are:  
  • Oscillatory devices  | Comparators of interest are:  
  • Standard therapy  | Relevant outcomes include:  
  • Symptoms  
  • Quality of life  
  • Hospitalizations  
  • Medication use |

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); and respiratory conditions associated with neuromuscular disorders.

For individuals who have 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.

Clinical input, obtained in 2008, was supportive of the use of oscillatory devices to treat patients with CF and bronchiectasis in certain situations. 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. Thus, these devices may be considered medically necessary when chest physical therapy has failed or is unavailable, or is not tolerated by the patient.

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 (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. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

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

Other airway clearance techniques require active patient participation; these include autogenic drainage and positive expiratory pressure therapy. Autogenic drainage, developed in Belgium and commonly used in Europe, consists of a series of controlled breathing exercises and does not involve an oscillatory device. Positive expiratory pressure therapy requires patients to exhale through a resistor to produce positive expiratory pressures during a prolonged period of exhalation. It is hypothesized that the positive pressure supports the small airway such that the expiratory airflow can better mobilize secretions.

High-frequency chest wall oscillation 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 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 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, also known as chest physical therapy, in patients with cystic fibrosis. Daily percussion and postural drainage need 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 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. 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 e.g., in the immediate post-surgical period, is not included in the policy.

**Regulatory Status**

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<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 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>
</tr>
<tr>
<td>AerobiKA oscillating PEP device</td>
<td>Trudell Medical</td>
<td>2013</td>
</tr>
<tr>
<td>Vibralung Acoustical Percussor</td>
<td>Westmed</td>
<td>2014</td>
</tr>
<tr>
<td>The vest airway clearance system</td>
<td>Hill-Rom</td>
<td>2015</td>
</tr>
<tr>
<td>The Monarch™ Airway Clearance System</td>
<td>Hill-Rom</td>
<td>2017</td>
</tr>
</tbody>
</table>

PEP: positive expiratory pressure.

**Rationale**

This evidence review was created in November 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through April 9, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more
intended clinical use of the technology in the intended population and compare an
effective and appropriate alternative at a comparable intensity. For some
conditions, the alternative will be supportive care or surveillance. The quality and
credibility of the evidence depend on study design and conduct, minimizing bias
and confounding that can generate incorrect findings. The randomized controlled
trial (RCT) is preferred to assess efficacy; however, in some circumstances,
nonrandomized studies may be adequate. RCTs are rarely large enough or long
enough to capture less common adverse events and long-term effects. Other types
of studies can be used for these purposes and to assess generalizability to broader
clinical populations and settings of clinical practice.

**Cystic Fibrosis**

**Clinical Context and Therapy Purpose**
The purpose of oscillatory positive expiratory pressure (PEP) therapy in patients
who have cystic fibrosis (CF) is to provide a treatment option that is an alternative
to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of oscillatory devices
improve health outcomes in patients with CF?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals with cystic fibrosis.

**Interventions**
The therapy being considered is the application of oscillatory PEP.

**Comparators**
The following therapy is currently being used: standard chest physical therapy.

**Outcomes**
The general outcomes of interest are reductions in respiratory symptoms due to
airway restrictions caused by a mucous buildup in the lungs.

**Timing**
Changes in outcomes over a minimum 3-month period should be considered
meaningful.

**Setting**
Oscillatory PEP devices are intended to be used primarily in home setting by
patients themselves.

**Systematic Reviews**
A number of RCTs and a Cochrane systematic review of RCTs have evaluated
oscillatory devices for treating patients with CF. The Cochrane review addressed a
variety of oscillatory devices and was last updated by Morrison and Agnew
and is summarized in Table 2. 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 the superiority of oscillatory devices vs any other form of physical therapy or that 1 device was superior over another and that there is a need for adequately powered RCTs with long-term follow-up.

Table 2. Characteristics of Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morrison et al (2014)</td>
<td>1995-2014</td>
<td>35a</td>
<td>Patients with cystic fibrosis</td>
<td>1050 (5-166)</td>
<td>RCT and controlled studies</td>
<td>1 wk to 1 y</td>
</tr>
</tbody>
</table>

a Ten were published only as abstracts, 16 were conducted in the United States, and 14 were single-center studies.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 3 and 4. Gaps related to relevance, study design, and conduct are summarized in Tables 5 and 6.

Mcllwaine et al (2013) published an RCT comparing high-frequency chest wall oscillation (HFCWO) with PEP mask therapy. The primary outcome measure was the number of pulmonary exacerbations requiring an antibiotic. At the end of 1 year, patients in the PEP arm had a statistically significant lower incidence of pulmonary exacerbations requiring antibiotics compared with HFCWO group. The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group (p=0.02). There were no statistically significant differences in pulmonary measures, including the forced expiratory volume in 1 second (FEV₁).

Sontag et al (2010) published a multicenter RCT that compared postural drainage, the Flutter device, and HFCWO. At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat analysis found no significant differences between treatment groups in the modeled rate of decline for percent predicted FEV₁ or forced vital capacity (FVC). The small sample size and high dropout rate limited the conclusions 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. Sixty-five (87%) of 75 patients completed the trial and were included in the analysis. Although the study was described as a noninferiority trial, it was not statistically analyzed as such. Instead, no statistically significant differences among the regimens in the primary outcome measure of FEV₁ were construed as evidence for noninferiority.
### Table 3. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>McIlwaine et al (2013)²</td>
<td>Canada</td>
<td>12</td>
<td>2008-2012</td>
<td>Children with CF age &gt;6 y (n=107)</td>
<td>HFCWO (n=56) Active</td>
</tr>
<tr>
<td>Sontag et al (2010)³</td>
<td>U.S.</td>
<td>20</td>
<td>1999-2002</td>
<td>Adults and children with CF (n=166)</td>
<td>2 active Tx: flutter (n=58) and vest (n=57) Postural drainage (n=58)</td>
</tr>
<tr>
<td>Pryor et al (2010)⁴</td>
<td>U.K.</td>
<td>1</td>
<td>NR</td>
<td>Patients with CF ≥16 y (n=75)</td>
<td>Cornet (n=15), Flutter (n=15), PEP (n=15), autogenic drainage (n=15)</td>
</tr>
</tbody>
</table>

CF: cystic fibrosis; HFCWO: high-frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial; Tx: treatment.

### Table 4. Summary of Key RCT Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of PEs Requiring Antibiotics</th>
<th>Spirometry</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>McIlwaine et al (2013)²</td>
<td>88</td>
<td>Cannot confirm</td>
<td>Not applicable</td>
</tr>
<tr>
<td>HFCWO</td>
<td></td>
<td>Data not reported</td>
<td>Outcome not evaluated</td>
</tr>
<tr>
<td>N</td>
<td>96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>2.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>1.00-3.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive expiratory pressure</td>
<td></td>
<td>Data not reported</td>
<td>Outcome not evaluated</td>
</tr>
<tr>
<td>N</td>
<td>49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0.00-2.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>0.007</td>
<td>No difference</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Sontag et al (2010)³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flutter</td>
<td>Outcome not evaluated</td>
<td>Data not reported</td>
<td>Outcome not evaluated</td>
</tr>
<tr>
<td>Vest</td>
<td>Outcome not evaluated</td>
<td>Data not reported</td>
<td>Outcome not evaluated</td>
</tr>
<tr>
<td>Postural drainage</td>
<td>Outcome not evaluated</td>
<td>Data not reported</td>
<td>Outcome not evaluated</td>
</tr>
<tr>
<td>p</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pryor et al (2010)⁴</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active cycle of breathing techniques</td>
<td>Outcome not evaluated</td>
<td>FEV₁ at 0 mo: 2.01 FEV₁ at 12 mo: 1.94</td>
<td>Small improvement (0.7)ᵃ</td>
</tr>
<tr>
<td>Autogenic drainage</td>
<td>Outcome not evaluated</td>
<td>FEV₁ at 0 mo: 2.68 FEV₁ at 12 mo: 2.64</td>
<td>Small improvement (0.5)ᵃ</td>
</tr>
<tr>
<td>Cornet</td>
<td>Outcome not evaluated</td>
<td>FEV₁ at 0 mo: 1.93 FEV₁ at 12 mo: 1.90</td>
<td>No difference (&lt;0.5)ᵃ</td>
</tr>
<tr>
<td>Flutter</td>
<td>Outcome not evaluated</td>
<td>FEV₁ at 0 mo: 2.46 FEV₁ at 12 mo: 2.43</td>
<td>Moderate improvement (1.3)ᵃ</td>
</tr>
<tr>
<td>Positive expiratory pressure</td>
<td>Outcome not evaluated</td>
<td>FEV₁ at 0 mo: 2.17 FEV₁ at 12 mo: 2.02</td>
<td>Small improvement (0.8)ᵃ</td>
</tr>
</tbody>
</table>
FEV₁: forced expiratory volume in 1 second; HFCWO: high-frequency chest wall oscillation; PE: pulmonary exacerbations; RCT: randomized controlled trial.

a Minimal important differences in the Chronic Respiratory Questionnaire. A change of 0.5 represents a small difference in symptoms, 1.0 a moderate difference, and 1.5 a large difference.

Table 5. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mcllwaine et al (2013)²</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sontag et al (2010)³</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pryor et al (2010)⁴</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mcllwaine et al (2013)²</td>
<td>3. Allocation concealment unclear</td>
<td>1. Not blinded to treatment assignment</td>
<td>1. Eighty-eight (82%) of 107 randomized patients completed the trial. Trial limitations were a nearly 20% dropout rate.</td>
<td>4. Trial stopped early without enrolling expected number of patients and might have been underpowered to detect clinically significant differences between groups</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sontag et al. (2010)  
3. Allocation concealment unclear  
1. Not blinded to treatment assignment  
1. Dropout rates were high; trial ended early: 35 (60%), 16 (31%), and 5 (9%) patients withdrew from the postural drainage, Flutter, and Vest groups, respectively. Most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13) and lack of time (n=7).  
4. Trial ended earlier than planned

Pryor et al. (2010)  
3. Allocation concealment unclear  
1. Not blinded to treatment assignment  
1. Ten of 75 randomized patients were lost to follow-up

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

FEV$_1$: forced expiratory volume in 1 second.

- **Blinding key**: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
- **Selective Reporting key**: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **Follow-Up key**: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- **Power key**: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
- **Statistical key**: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Section Summary: Cystic Fibrosis**

A number of RCTs evaluating oscillatory devices have reported 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 techniques; some were published only as abstracts. The study findings were not pooled due to heterogeneity in designs and outcome measures. A 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 CF.
Other Respiratory Disorders

Clinical Context and Therapy Purpose
The purpose of oscillatory PEP therapy in patients who have other respiratory disorders (eg, bronchiectasis, chronic obstructive pulmonary disease [COPD], respiratory conditions related to neuromuscular disorders) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of oscillatory devices improve health outcomes in patients with other respiratory disorders (eg, bronchiectasis, COPD, respiratory conditions related to neuromuscular disorders)?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with other respiratory disorders (eg, bronchiectasis, COPD, respiratory conditions related to neuromuscular disorders).

Interventions
The therapy being considered is the application of an oscillatory PEP.

Comparators
The following therapy is currently being used: standard chest physical therapy or standard therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (eg, pulmonary exacerbations).

Timing
Changes in outcomes over a minimum 3-month period should be considered meaningful.

Setting
Oscillatory PEP devices are intended to be used primarily in home setting by patients themselves.

Bronchiectasis
Lee et al (2015) published a Cochrane review of airway clearance techniques for treating bronchiectasis, which is summarized in Table 7.5. Of 7 RCTs included, 6 were crossover trials. 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 were pulmonary exacerbations, hospitalizations for bronchiectasis, and QOL.
### Table 7. Characteristics of Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee et al (2015)</td>
<td>1966-2015</td>
<td>7 RCTs</td>
<td>Adults and children diagnosed with bronchiectasis based on plain-film chest radiography, bronchography, high-resolution computed tomography or physician diagnosis</td>
<td>1107 (8-37)</td>
<td>1 RCT, 6 crossover RCTs</td>
<td>Immediate (within 24 h) and “long-term” (&gt;24 h)</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 8 and 9. Gaps related to relevance, study design, and conduct are summarized in Tables 10 and 11. Murray et al (2009) reported on a crossover study with 20 patients. The number of exacerbations did not differ statistically at 12 weeks.² Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Cochrane reviewers noted that the study was not blinded, and that patient-reported QOL measures may have been subject to bias.

Herrero-Cortina et al (2016) reported on a crossover RCT with 31 patients.³ The interventions were temporary PEP, autogenic drainage, and slow expiration with the glottis opened in the lateral position. 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).

### Table 8. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herrero-Cortina et al</td>
<td>Spain</td>
<td>1</td>
<td>2010-2013</td>
<td>Patients radiologically diagnosed with bronchiectasis (n=31)</td>
<td>Slow expiration with glottis opened in lateral posture (n=31) and temporary PEP (n=31)</td>
</tr>
</tbody>
</table>

NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial.

### Table 9. Summary of Key RCT Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Total LCQ Score Difference Median (IQR)</th>
<th>24-h Sputum Volume Difference, mL Median (IQR)</th>
<th>No. of Exacerbations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murray et al (2009)</td>
<td>20</td>
<td>20</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Acapella</td>
<td>1.3 (-0.17-3.25)</td>
<td>2 (0-6)</td>
<td>5</td>
</tr>
<tr>
<td>No Acapella</td>
<td>0 (-1.5-0.5)</td>
<td>-1 (-5 to 0)</td>
<td>7</td>
</tr>
<tr>
<td>p</td>
<td>0.002</td>
<td>0.02</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Change (95% CI); p

Herrero-Cortina et al (2016)

Autogenic drainage

0.5 (0.1 to 0.5); 0.01  

-1.4 (5.1 to 1.2)  

Not studied
Table 10. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herrero-Cortina et al (2016)</td>
<td>1, 2. Only 24-h follow-up is not enough</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

- Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

- Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.


Table 11. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.


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 COPD. Both reviews addressed various techniques (ie, they were not limited to studies on oscillatory devices) and are summarized in Table 12. Studies included in both the systematic reviews were largely small and none conducted a meta-analysis. Reviewers noted that quality of evidence was generally poor.

Table 12. Characteristics of Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osadnik et al (2012)</td>
<td>Inception to 2009</td>
<td>28</td>
<td>Participants with investigator-defined COPD, emphysema or chronic bronchitis</td>
<td>907 (5-96)</td>
<td>RCTs (parallel and crossover) &gt;8 wk</td>
<td></td>
</tr>
</tbody>
</table>

| CAGR: Cochrane Airways Group Specialised Register of trials; COPD: chronic obstructive pulmonary disease; PEDro: Physiotherapy Evidence Database; RCT: randomized controlled trial. |

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 13 and 14. Gaps related to relevance, study design and conduct are summarized in Tables 15 and 16.

Chakroverty et al (2011) reported results of a crossover RCT among 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. 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 was no significant pre- to posttreatment differences in secondary outcomes (eg, FEV$_1$, FVC).

Svenningsen et al (2016) reported on results of an unblinded, industry-funded, randomized crossover study. Each intervention period lasted 21 to 28 days. In the nonsputum producers, scores differed significantly only on the Patient Evaluation Questionnaire total score. In patients who were sputum-producers at baseline, pre- vs post-PEP scores differed significantly for FVC, 6-minute walk distance, SGRQ total score, and the Patient Evaluation Questionnaire ease of bringing up sputum and patient global assessment subscales. It is unclear if the interventions were clinically meaningful. The crossover studies had similar limitations including no between-group comparisons (ie, outcomes after oscillatory device use vs the control intervention), lack of intention-to-treat analysis, and short-term follow-up (immediate posttreatment period).

Goktalay et al (2013) reported on the results of a parallel-group RCT. Patients were randomized to 5 days of treatment with medical therapy plus HFCWO (n=25) or medical therapy only (n=25). At day 5, outcomes including FEV$_1$, modified Medical Research Council dyspnea scale scores, and the 6-minute walk 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.

### Table 13. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chakrovorty et al (2011)</td>
<td>U.K.</td>
<td>1</td>
<td>NR</td>
<td>Patients with at least 1 COPD exacerbation with FEV$_1$ &lt;0.8, FEV$_1$/FVC &lt;0.7, and a daily wet sputum volume of &gt;25 mL (n=38)</td>
<td>SmartVest Airway Clearance System (n=22)</td>
<td>No SmartVest Airway Clearance System (n=22)</td>
</tr>
<tr>
<td>Svenningsen et al (2016)</td>
<td>Canada</td>
<td>1</td>
<td>NR</td>
<td>COPD patients self-identified as sputum-producers or non-sputum-producers (n=32)</td>
<td>Oscillatory PEP (AerobiKA device) (n=27)</td>
<td>No oscillatory PEP (n=27)</td>
</tr>
<tr>
<td>Goktalay et al (2013)</td>
<td>Turkey</td>
<td>1</td>
<td>2009-2011</td>
<td>Patients with stage 3 or 4 COPD hospitalized for COPD exacerbations (n=50)</td>
<td>HFCWO plus medical Tx (n=25)</td>
<td>Medical Tx only (n=25)</td>
</tr>
</tbody>
</table>

COPD: chronic obstructive pulmonary disease; FEV$_1$: forced expiratory volume in 1 second; FVC: forced vital capacity; HFCWO: high-frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial; Tx: treatment.
### Table 14. Summary of Key RCT Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>SGRO Total Scores</th>
<th>BODE Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chakrovorty et al (2011)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SmartVest</td>
<td>Baseline: 63</td>
<td>End of treatment: 60</td>
</tr>
<tr>
<td>No SmartVest</td>
<td>Baseline: 62</td>
<td>End of treatment: 62</td>
</tr>
<tr>
<td>p</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Svenningsen et al (2016)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oscillatory positive expiratory pressure</td>
<td>Sputum-producers: 40 (12)</td>
<td>Non-sputum-producers: 36</td>
</tr>
<tr>
<td>Control</td>
<td>Sputum-producers: 49</td>
<td>Non-sputum-producers: 35</td>
</tr>
<tr>
<td>p</td>
<td>0.01 (sputum-producers)</td>
<td>0.64 (non-sputum-producers)</td>
</tr>
<tr>
<td>Goktalay et al (2013)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HFCWO plus medical treatment</td>
<td>Not assessed</td>
<td></td>
</tr>
<tr>
<td>Medical treatment only</td>
<td>Not assessed</td>
<td>Daily: 7.72</td>
</tr>
<tr>
<td>p</td>
<td>Not applicable</td>
<td>Day 3: 7.48</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Day 5: 7.24</td>
</tr>
</tbody>
</table>

BODE: body mass index, airflow obstruction, dyspnea, and exercise; HFCWO: high-frequency chest wall oscillation; RCT: randomized controlled trial; SGRO: St George’s Respiratory Questionnaire.

### Table 15. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chakrovorty et al (2011)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Svenningsen et al (2016)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goktalay et al (2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
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</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

### Table 16. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chakrovorty et al (2011)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Allocation concealment unclear</td>
<td>1. Not blinded to treatment assignment</td>
<td>1. High loss to follow-up or missing data: 8 out of 30 withdrew due to COPD exacerbations</td>
<td>2. Power not calculated for primary outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>Allocation Concealment</td>
<td>Outcome Assessed</td>
<td>Loss to Follow-Up or Missing Data</td>
<td>Power</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>------------------------</td>
<td>------------------</td>
<td>-----------------------------------</td>
<td>-------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Svenningsen et al (2016)</td>
<td>Not Blinded</td>
<td>Treated Physician</td>
<td>16% withdrew from trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>allocated</td>
<td>to treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>assignment</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

COPD: chronic obstructive pulmonary disease.


d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.

f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**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 intention-to-treat analysis and between-group comparisons. The published studies reported mixed findings and did not support the use of oscillatory devices in COPD patients.

**Respiratory Conditions Related to Neuromuscular Disorders Children**

A Cochrane review by Winfield et al (2014) evaluated the nonpharmacologic management of respiratory morbidity in children with severe global developmental delay treated with airway clearance techniques.13 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. As a result of heterogeneity, a meta-analysis was not conducted. It is summarized in Table 17.

### Table 17. Characteristics of Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Winfield et al (2014)</td>
<td>Inception to Nov 2013</td>
<td>15</td>
<td>Children up to 18 y with a diagnosis of severe neurologic impairment and respiratory morbidity</td>
<td>Not reported</td>
<td>RCTs and nonrandomized comparative studies</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 18 and 19. Gaps related to relevance, study design and conduct are summarized in Tables 20 and 21.

Yuan et al (2010) reported results of a parallel-arm RCT. Both groups were instructed to perform the assigned treatment for 12 minutes, 3 times a day for the study period (mean, 5 months). There were no statistically significant differences between groups on primary outcomes. No therapy-related adverse events were reported in either group.

Lange et al (2006) reported on results of a parallel-arm RCT in adults with amyotrophic lateral sclerosis. Patients were randomized to 12 weeks of HCFWO or usual care. 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 amyotrophic lateral sclerosis 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.

### Table 18. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuan et al (2010)</td>
<td>U.S.</td>
<td>1</td>
<td>NR</td>
<td>Patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic (n=28)</td>
<td>HCFWO (n=12) Standard chest physical therapy (n=11)</td>
</tr>
<tr>
<td>Lange et al (2006)</td>
<td>U.S.</td>
<td>6</td>
<td>NR</td>
<td>Adults with amyotrophic lateral sclerosis (n=46).</td>
<td>HCFWO (n=22) No treatment (n=24)</td>
</tr>
</tbody>
</table>

HCFWO: high-frequency chest wall oscillation; NR: not reported; RCT: randomized controlled trial.

### Table 19. Summary of Key RCT Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Hospitalization/IV Antibiotics</th>
<th>TDI (proportion showing worsening)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuan et al (2010)</td>
<td>23</td>
<td>0/12</td>
</tr>
<tr>
<td>HCFWO</td>
<td></td>
<td>Not assessed</td>
</tr>
</tbody>
</table>
### HFCWO: high-frequency chest wall oscillation; IV: intravenous; RCT: randomized controlled trial; TDI: Transitional Dyspnea Index

#### Table 20. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuan et al (2010)</td>
<td>1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- **Population key:**
  - 1. Intended use population unclear
  - 2. Clinical context is unclear
  - 3. Study population is unclear
  - 4. Study population not representative of intended use

- **Intervention key:**
  - 1. Not clearly defined
  - 2. Version used unclear
  - 3. Delivery not similar intensity as comparator
  - 4. Not the intervention of interest

- **Comparator key:**
  - 1. Not clearly defined
  - 2. Not standard or optimal
  - 3. Delivery not similar intensity as intervention
  - 4. Not delivered effectively

- **Outcomes key:**
  - 1. Key health outcomes not addressed
  - 2. Physiologic measures, not validated surrogates
  - 3. No CONSORT reporting of harms
  - 4. Not establish and validated measurements
  - 5. Clinical significant difference not prespecified
  - 6. Clinical significant difference not supported

- **Follow-Up key:**
  - 1. Not sufficient duration for benefit
  - 2. Not sufficient duration for harms

#### Table 21. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yuan et al (2010)</td>
<td>1. Allocation concealment unclear</td>
<td>1. Not blinded to treatment assignment 2. Not blinded outcome assessment (except chest X-rays) 3. Outcome assessed by treating physician</td>
<td>1. High loss to follow-up or missing data 12% missing data and all in treatment group</td>
<td>1, 2, 3. Trial was exploratory and was not powered to detect statistically significant findings on of the primary outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

HFCWO: high-frequency chest wall oscillation.

- Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
- Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Section Summary: Respiratory Conditions Related to Neuromuscular Disorders**

Two RCTs and a systematic review have evaluated oscillatory devices for treatment of respiratory conditions in neuromuscular disorders. One RCT was not powered to detect statistical significance. The other, conducted in amyotrophic lateral sclerosis patients, did not find statistically significant improvement after HFCWO compared with usual care for the primary outcomes (pulmonary function measures) or most secondary outcomes.

**Summary of Evidence**

For individuals who have cystic fibrosis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. The RCTs reported 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. Reviewers could not pool findings due to heterogeneity in study designs and outcome measures and concluded that additional adequately powered RCTs with long-term follow-up would be 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 one 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 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 chronic obstructive pulmonary disease, 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 reported mixed findings and did not clearly support the use of oscillatory devices in this population. 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 statistically significant differences. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvements after high-frequency chest wall compression devices vs 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, input was received from 2 academic medical centers while this policy was under review 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. Input did not support the 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.\textsuperscript{16}

**Cystic Fibrosis Foundation**
The Cystic Fibrosis Foundation (2009) published guidelines on airway clearance therapies based on a systematic review of evidence.\textsuperscript{17} 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 22.

**Table 22. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03013452</td>
<td>Oscillating PEP vs Autogenic Drainage in People With Bronchiectasis (oPEP-vs-AD)</td>
<td>50</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

**REFERENCES**

Billing Coding/Physician Documentation Information

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
E0480  Percussor, electric or pneumatic, home model
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

ICD10 Codes:
E84.0-  Cystic fibrosis code range
E84.9
J47.1-  Bronchiectasis code range
J47.9

Additional Policy Key Words
N/A

Policy Implementation/Update Information
3/1/01  New policy. Added to DME section, considered medically necessary with criteria.
3/1/02  No policy statement changes.
3/1/03  No policy statement changes.
6/1/04  Policy statement revised to indicate devices are either not medically necessary or investigational depending on indication. However, special consideration may be given to individual patients meeting criteria.
3/1/05  No policy statement changes.
3/1/06  No policy statement changes.
3/1/07  Policy updated to remove individual consideration indications. The effective date of the change is 8/15/07.
3/1/08  No policy statement changes.
12/11/08  Interim Change. Policy statements changed to indicate high-frequency chest wall compression devices may be medically necessary in cystic fibrosis and chronic bronchiectasis when specific criteria are met and that flutter valves and Acapella device may be considered medically necessary in some cases of hypersecretory chronic lung diseases. Chest wall compression devices remain investigational for other conditions such as COPD.
3/1/09  No policy statement changes.
3/1/10  No policy statement changes.
5/1/10  Policy statements changed to indicate intrapulmonary percussive devices may be medically necessary in cystic fibrosis and chronic bronchiectasis when specific criteria are met. (Same as criteria for high-frequency chest wall compression devices).
3/1/11  No policy statement changes.
3/1/12  No policy statement changes.
3/1/13  No policy statement changes.
3/1/14  In first 2 medically necessary statements, Flutter valve or Acapella device changed to oscillatory positive expiratory pressure device. In second policy statement, “standard chest physiotherapy treatment” changed to “standard treatment”. Added cpt for 2014.
3/1/15  No policy statement changes.
3/1/16  No policy statement changes.
8/1/16  In title, “disorders” changed to “conditions”. No other policy statement changes.
3/1/17  No policy statement changes.
8/1/17  ’Not medically necessary’ statement removed and “patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above” added to the investigational statement.
3/1/18  No policy statement changes.
3/1/19  No policy statement changes.
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