FEP 1.01.15 Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

**Effective Date:** October 15, 2018  
**Related Policies:** None

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

**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.

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, the 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 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, ThAirRapy 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...
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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 check 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.

**OBJECTIVE**

The objective of this evidence review is to determine whether oscillatory devices improve the net health outcome in patients with cystic fibrosis and other respiratory disorders. This evidence review addresses the outpatient use of oscillatory devices. We do not address inpatient device use (eg, in the immediate postsurgical period) here.

**POLICY STATEMENT**

Use of an oscillatory positive expiratory pressure device may be considered *medically necessary* in patients with hypersecretory lung disease (ie, 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 Policy Guidelines section) (including chest computed tomography scan) when standard chest physical therapy has failed or standard chest physical therapy is unavailable or not tolerated. In considering the chest wall compression and intrapulmonary percussive ventilation devices, there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments (ie, the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment [chest physical therapy and, if appropriate, use of an oscillatory positive expiratory pressure 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, 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*.

**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 2 times per year 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, manual percussion and postural drainage 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.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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 have not suggested that these devices are associated with an increased health benefit, their use would primarily represent a convenience to the patient. It is on this basis that they are considered not medically necessary (unless conventional chest physical therapy has failed or is unavailable).

**FDA 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. Select 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>Flutter® Mucus Clearance Device</td>
<td>Axcan Scandipharm (for marketing in the United States)</td>
<td>1994</td>
</tr>
<tr>
<td>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>
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<td>PEP: positive expiratory pressure.</td>
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</table>

Food and Drug Administration product codes: BYI, BYT.

**RATIONALE**

**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

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.16

Cystic Fibrosis Foundation
The Cystic Fibrosis Foundation (2009) published guidelines on airway clearance therapies based on a systematic review of evidence.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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

FEP 1.01.15 Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
### POLICY HISTORY

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<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review. References 12, 13 and 14 added;</td>
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<td></td>
<td>other references renumbered or removed. No change in policy statement.</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 2, 7, 8, 9, and 13 added;</td>
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<tr>
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<td></td>
<td>“standard chest physiotherapy treatment” changed to &quot;standard treatment&quot;.</td>
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<tr>
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<td>with neuromuscular disorders added to investigational statement. In title,</td>
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<td>above” added to the investigational statement.</td>
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