MEDICAL POLICY – 1.01.15
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

BCBSA Ref. Policy: 1.01.15
Effective Date: Sept. 1, 2019
Last Revised: Aug. 6, 2019
Replaces: N/A
RELATED MEDICAL POLICIES: None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Certain diseases like cystic fibrosis can cause a lot of sticky mucus in the lungs. Clearing the mucus helps prevent infection and inflammation. Chest physiotherapy, also called manual chest physical therapy, is the standard way of clearing airways. Devices that vibrate, called oscillators, may also be used in certain situations. An oscillating positive expiratory pressure device (PEP) creates vibrations as a person breathes into a handheld device. A high-frequency chest wall oscillation device uses an inflatable vest attached to a machine. The device causes the vest to inflate and deflate very fast to loosen the mucus. An intrapulmonary percussive ventilator gives fast bursts of air through a mouthpiece and into the airway. This allows the mucus to be coughed out or suctioned. This policy describes when specific oscillatory devices may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive expiratory pressure device</td>
<td>Use of an oscillatory positive expiratory pressure 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.</td>
</tr>
</tbody>
</table>
| High-frequency chest wall compression devices | 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 (including chest computed tomography [CT] 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 (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).  

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

### Device

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 not medically necessary.</td>
</tr>
</tbody>
</table>

### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- History and physical with relevant diagnoses or conditions.
- Documentation that patients have difficulty clearing secretions and have recurrent disease exacerbations
- For high-frequency chest wall compression devices or intrapulmonary percussive ventilation devices, in addition to the above also include the following:
  - Documented need for airway clearance
  - Documented failure of standard chest physical therapy OR standard chest physical therapy cannot be tolerated or is unavailable

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each</td>
</tr>
<tr>
<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each</td>
</tr>
</tbody>
</table>
### Related Information

**Benefit Application**

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).

**Evidence Review**

**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 therapists and other providers may also use oscillatory devices for other respiratory conditions such as diffuse bronchiectasis, chronic obstructive pulmonary disease, and respiratory conditions associated with neuromuscular disorders.
Background

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra or extra thoracic. 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 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 (eg, the Vest Airway Clearance System, ThAIRapy Bronchial Drainage System, SmartVest Airway Clearance System) are passive oscillatory devices designed to provide airway clearance without 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 a type of passive oscillatory device; it delivers intrapulmonary percussive ventilation. This device combines internal thoracic percussion through rapid mini bursts of inhaled air with 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 policy addresses the outpatient use of oscillatory devices. We do not address inpatient device use (eg, in the immediate postsurgical period) here.

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, frequency of 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 technique; 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 improvement after high-frequency chest
cell 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. 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.
* No results posted on clinicaltrials.gov website as of 05/10/19.

Clinical Input Received From Physician Specialty Societies and Academic
Medical Centers

While the various physician specialty societies and academic medical centers may collaborate
with and make recommendations during this process, through the provision of appropriate
reviewers, input received does not represent an endorsement or position statement by the
physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from two 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 use of oscillatory devices for the 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.\(^{15}\)

**Cystic Fibrosis Foundation**

The Cystic Fibrosis Foundation (2009) published guidelines on airway clearance therapies based on a systematic review of evidence.\(^{16}\) 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).

**Medicare National Coverage**

There is no national coverage determination.

**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 2.

**Table 2. 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</td>
<td>1994</td>
</tr>
</tbody>
</table>

Augment the text.
<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

PEP: positive expiratory pressure.

Food and Drug Administration product codes: BYI, BYT.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/10/11</td>
<td>Add to Durable Medical Equipment Section - New medical policy. This policy replaced 1.01.115.</td>
</tr>
<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature review. References 12, 13 and 14 added. No changes to policy statements.</td>
</tr>
<tr>
<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>04/16/13</td>
<td>Replace Policy. Rationale section for COPD updated based on literature review through January 2013. References 13, 14 added; others renumbered or removed. Policy statement unchanged.</td>
</tr>
<tr>
<td>04/14/14</td>
<td>Annual Review. In first 2 medically necessary statements, brand named Flutter or Flutter and Acapella devices changed to generic “oscillatory positive expiratory pressure device”. In second policy statement, “standard chest physiotherapy treatment” changed to “standard treatment”. Policy updated with literature review through December 20, 2013. References 2, 7, 8, 9 and 13 added; others renumbered/removed. Policy statements wording changed as noted, intent unchanged. Coding update; ICD-9 procedure code 93.18 and ICD-10 PCS codes; HCPCS code S8185 removed – this is a low dollar item.</td>
</tr>
<tr>
<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through December 15, 2014. Reference 1 added. Policy statements unchanged. Remove ICD-9 and ICD-10 codes removed; these are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/01/16</td>
<td>Annual Review, approved August 9, 2016. Policy updated with literature review through April 25, 2016; references 5, 12, and 14-16 added. Patients with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, “disorders” changed to “conditions”.</td>
</tr>
<tr>
<td>04/11/17</td>
<td>Policy moved into new format. Reformatted the Evidence Review section. No change to policy statements.</td>
</tr>
<tr>
<td>08/01/17</td>
<td>Annual Review, approved July 18, 2017. Policy updated with literature review through April 25, 2017; reference 9 added. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered not medically necessary when criteria are not met (previously considered investigational).</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; no references were added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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