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

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EVIDENCE REVIEW | REFERENCES | HISTORY

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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 machine 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 (PEP) 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.</td>
</tr>
<tr>
<td>High-frequency chest wall compression devices</td>
<td>High-frequency chest wall compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered medically necessary in patients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography[CT] scan) when:</td>
</tr>
<tr>
<td>Intrapulmonary percussive ventilation devices</td>
<td>• Standard chest physical therapy has failed OR • Standard chest physical therapy is unavailable or not tolerated</td>
</tr>
</tbody>
</table>

In considering the chest wall compression and IPV devices, there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments, ie, the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physical therapy and, if appropriate, use of an oscillatory PEP device) or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.

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.
Device | Medical Necessity
--- | ---
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.

<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-frequency chest wall compression devices</td>
<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>
<tr>
<td>Intrapulmonary percussive ventilation devices</td>
<td></td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each</td>
</tr>
<tr>
<td>A7026</td>
<td>High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each</td>
</tr>
<tr>
<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and related accessories</td>
</tr>
<tr>
<td>E0483</td>
<td>High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
</tr>
<tr>
<td>E0484</td>
<td>Oscillatory positive expiratory pressure device, non-electric, any type, each</td>
</tr>
</tbody>
</table>

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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, 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 (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 that delivers intrapulmonary percussive ventilation. This device combines internal thoracic percussion through rapid minibursts 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 the drainage and clearance of bronchial secretions, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. Additionally, these devices could benefit patients with neuromuscular diseases who have an impaired ability to cough and clear their secretions.

This policy addresses outpatient use of oscillatory devices. Inpatient device use, eg, in the immediate post-surgical period, is not included in the policy.

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 had mixed findings and limitations such as small sample sizes and large dropout rates. A systematic review identified 35 RCTs comparing oscillatory devices with other recognized airway clearance techniques.
techniques; some were published only as abstracts. The review authors could not pool findings due to heterogeneity in study designs and outcome measures, and they concluded that additional adequately powered RCTs with long-term follow up are needed to make conclusions about oscillatory devices for cystic fibrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have COPD who receive oscillatory devices, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tend to have small sample sizes, short follow-up periods, and limitations in their analyses (eg, there was a lack of an 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.

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.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, 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. Clinical 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 CF, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physical therapy.18
**Cystic Fibrosis Foundation**

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

**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.

**Regulatory Status**

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process including the following 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>Bird IPV® Noncontinuous Ventilator</td>
<td>Percussionaire Corp.</td>
<td>1989</td>
</tr>
<tr>
<td>Flutter® Mucus Clearance Device</td>
<td>Axcan Scandipharm (for marketing in the United States)</td>
<td>1994</td>
</tr>
<tr>
<td>ThAIRapy Bronchial Drainage System (Vest™ Airway Clearance System)</td>
<td>Hill-Rom</td>
<td>1998</td>
</tr>
<tr>
<td>Acapella® device</td>
<td>DHD Healthcare</td>
<td>1999</td>
</tr>
<tr>
<td>RC 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>
</tbody>
</table>

PEP: positive expiratory pressure.

FDA product codes: BYI, BYT.


### 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>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</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
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Tsaab ntawv tshaj xo no muaj cov ntsibab lus tseem ceeb. Tej zaum tsab ntawv tshaj xo no muaj cov ntsibab lus tseem ceeb bokj kaj dawl ntawv thov kev pab los yog kaj chov kev pab cuam los ntawv Premera Blue Cross. Tej zaum muaj cov hnb tseem ceeb cuam rau hauv daim ntawv no. Tej zaum kaj koy yawu taq uu qee yam uas peb kom kaj uas tis pub dhaas cov cajy ngoy uas teev tseg rau hauv daim ntawv no mas kaj koy yawu taq bas kev pab cuam kho moh los yog kev pab them tej niq kho moh ntawv. Kaj muaj cai kom laww muab cov ntsibab lus no uas tau muab sau uq kaj hom lus pub dawb rau kaj. Hu rau 800-722-1471 (TTY: 800-842-5357).

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Daytoy a Pakdaa ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaa mabal cin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonoy wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalbin dagiti importante a pesa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramideny nga addang saktay dagiti partikular a naituding nga aidaw tapno mapatgalaineyo a ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodoy a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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