

Protocol

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

(10115)

Medical Benefit		Effective Date: 01/01/18	Next Review Date: 07/21
Preauthorization	No	Review Dates: 01/07, 03/08, 03/09, 03/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 07/16, 07/17, 07/18, 05/20, 07/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
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

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.

SUMMARY OF EVIDENCE

For individuals who have cystic fibrosis who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. The RCTs reported mixed findings and limitations such as small sample sizes and large drop-out 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 seven small RCTs on several types of oscillatory devices; only one reported the clinically important outcomes of exacerbations or hospitalizations. Only three 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 supported the use of oscillatory devices to treat patients with cystic fibrosis 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, is unavailable, or is not tolerated by the patient.

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 (e.g., 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 two 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.

POLICY

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.

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 (see Policy Guidelines) (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 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 res-

piratory 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 protocol, chronic diffuse bronchiectasis is defined by a daily productive cough for at least six continuous months or exacerbations more than two times per year requiring antibiotic therapy and confirmed by high resolution or spiral chest computed tomography (CT) scan.

For the chest wall compression devices, a trial period to determine patient and family compliance may be considered. Those who appear to benefit most from the compression devices are adolescents and adults for whom, due to life-style factors, manual percussion and postural drainage may not be available.

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

MEDICARE ADVANTAGE

For Medicare Advantage high frequency chest wall oscillation devices are **medically necessary** for patients who meet:

- A. Criterion 1, 2 or 3, and
- B. Criterion 4
 1. There is a diagnosis of cystic fibrosis.
 2. There is a diagnosis of bronchiectasis characterized by a daily productive cough for a least six continuous months or frequent exacerbations requiring antibiotics (i.e., more than two/year) and confirmed by high resolution, spiral or standard CT scan.
 3. The patient has one of the following neuromuscular disease diagnoses: Post-polio, acid maltase deficiency, anterior horn cell diseases, multiple sclerosis, quadriplegia, hereditary muscular dystrophy, myotonic disorders, other myopathies, or paralysis of the diaphragm.
 4. There must be well-documented failure of standard treatments to adequately mobilize retained secretions.

An intrapulmonary percussive ventilator (IPV) has not been demonstrated to be reasonable and necessary in the home setting and is considered **not medically necessary**.

BACKGROUND

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require the active participation of patients. They include oscillating positive expira-

tory 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, ThAIRapy Bronchial Drainage System, SmartVest Airway Clearance System) are passive oscillatory devices designed to provide airway clearance without the active patient participation. The Vest Airway Clearance System provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator creates pressure pulses that inflate and deflate the vest against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

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

All of these techniques may be alternatives to daily percussion and postural drainage in patients with cystic fibrosis, also known as chest physical therapy. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, often a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles. Oscillatory devices can also potentially be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

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

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

Device	Manufacturer	Clearance Date
Flutter® Mucus Clearance Device	Axcan Scandipharm (for marketing in the United States)	1994
Vest™ Airway Clearance System	Hill-Rom	1998
Acapella® device	DHD Healthcare	1999
RC Cornet™ Mucus Clearing Device	PARI Respiratory Equipment	1999
inCourage® System	RespirTech	2005
AerobiKA oscillating PEP device	Trudell Medical	2013
Vibralung Acoustical Percussor	Westmed	2014
The vest airway clearance system	Hill-Rom	2015

Device	Manufacturer	Clearance Date
The Monarch™ Airway Clearance System	Hill-Rom	2017

PEP: positive expiratory pressure.

Food and Drug Administration product codes: BYI, BYT.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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