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

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required for the high-frequency chest wall compression device. 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.

Description

Oscillatory devices are used as 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. Oscillatory devices are also proposed for other respiratory conditions such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

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 (PEP) 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 require active patient participation. For example, autogenic drainage and active cycle of breathing technique both involve a combination of breathing exercises performed by the patient. PEP therapy requires patients to exhale through a resistor to produce PEPs 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.

In contrast, high-frequency chest wall oscillation (HFCWO) devices (e.g., the Vest Airway Clearance System, formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System) are passive oscillatory devices designed to provide airway clearance without the active participation of the patient. 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 cause the vest to inflate and deflate 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 or chest physiotherapy, in patients with cystic fibrosis. Daily percussion and postural drainage needs 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 wish to 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 COPD.

This Protocol addresses outpatient use of oscillatory devices. Inpatient device use, e.g., in the immediate postsurgical period, is not included in the Protocol.

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:

- The Bird IPV® Noncontinuous Ventilator (Percussionaire Corp) in 1989.
- Flutter® Mucus Clearance Device in 1994. The Flutter® device is currently marketed in the United States by Axcan.
- The ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by FDA—most recently a fifth generation device. The device is now known as the Vest™ Airway Clearance System, and it is manufactured by Hill-Rom.
- The Acapella® device (DHD Healthcare) in 1999.
- The RC Cornet™ Mucus Clearing Device (PARI Respiratory Equipment) in 1999.
- The inCourage® System (Respiratory Technologies; Lakeville, MN) in 2005.

Policy (Formerly Corporate Medical Guideline)
Use of an oscillatory 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 (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 [CT] 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 PEP device), or valid reasons why standard cannot be performed, such as inability of the caregiver to perform it.

High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered not medically necessary as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis in any other clinical situations; there are no clinical data to show that these devices provide any additional health benefit compared to conventional chest physical therapy in situations other than those specified here.

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation...
devices, including, but not limited to, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease, are considered investigational.

**Policy Guideline**

For this Protocol, chronic diffuse bronchiectasis is defined by daily productive cough for at least six continuous months or more than two 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 due to lifestyle factors in which manual percussion and postural drainage (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.

**Medicare Advantage**

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

A. Criteria 1, 2 or 3, and

B. Criteria 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.

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


16. National Government Services Local Coverage Determination (LCD): High Frequency Chest Wall Oscillation Devices (L12870), revision Effective Date For services performed on or after 05/01/2013.