

## Corporate Medical Policy

### Oscillatory Devices for the Treatment of Respiratory Conditions

<b>File Name:</b>	oscillatory_devices_for_treatment_of_respiratory_conditions
<b>Origination:</b>	3/1998
<b>Last CAP Review:</b>	3/2012
<b>Next CAP Review:</b>	3/2013
<b>Last Review:</b>	3/2012

#### Description of Procedure or Service

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Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) 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).

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 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 hand-held 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 exercised performed by the patient. Positive expiratory pressure (PEP) 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.

In contrast, high-frequency chest wall compression 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 the above techniques can be used as alternatives to daily percussion and postural drainage (P/PD), also known as chest physical therapy or chest physiotherapy, in patients with cystic fibrosis. P/PD 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

# Oscillatory Devices for the Treatment of Respiratory Conditions

diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

## 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 the 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.

*\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

## Policy

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**BCBSNC will provide coverage for oscillatory devices for the treatment of respiratory conditions when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.**

**BCBSNC will provide coverage for a flutter device when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Oscillatory Devices for the Treatment of Respiratory Conditions are covered

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Use of the FLUTTER® valve or Acapella® 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 devices may be considered **medically necessary** in patients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (see Policy Guidelines.)

## When Oscillatory Devices for the Treatment of Respiratory Conditions are not covered

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High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered **not medically necessary** as an alternative to chest physical therapy in cystic fibrosis and chronic bronchiectasis patients outside the clinical situations specified in this policy.

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

# Oscillatory Devices for the Treatment of Respiratory Conditions

use in other lung diseases, such as chronic obstructive pulmonary disease (COPD), are considered **investigational**.

## Policy Guidelines

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High frequency chest wall oscillation may be considered medically necessary when **ALL** of the following criteria are met:

- 1) The diagnosis is cystic fibrosis or chronic diffuse bronchiectasis. For the purposes of this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months, or more than two exacerbations per year, requiring antibiotic therapy, and confirmed by high resolution or spiral chest CT scan.
- 2) Effective chest physiotherapy is required. There should be demonstrated presence of bronchopulmonary secretions with need for airway clearance. The device should not be used prophylactically to prevent onset of respiratory symptoms.
- 3) Conventional manual CPT is unavailable, ineffective, or not tolerated. There should be documented failure of standard treatments (chest physiotherapy and, if appropriate, use of the FLUTTER® device), or valid reasons why standard chest physiotherapy cannot be performed.
- 4) A trial period is required to determine patient and family compliance. Sufficient and appropriate usage of the device during the trial period must be documented.
- 5) The device is prescribed by either a pulmonologist or a cystic fibrosis clinic.

Oscillatory devices are designed to move mucus and clear airways. In patients with cystic fibrosis, it is difficult to reach scientific conclusions regarding the relative efficacy of oscillatory therapies compared to standard treatment with daily percussion and postural drainage. However, findings from RCTs, combined with clinical input suggest that oscillatory devices may be comparable to chest physical therapy for cystic fibrosis patients in some situations. The available evidence and clinical input also suggest that oscillatory devices may be appropriate for treating diffuse bronchiectasis in similar situations. Thus, these devices may be considered medically necessary when chest physical therapy has failed or is unavailable or not tolerated by the patient. The sparse data do not suggest that any one oscillatory device is superior to another for cystic fibrosis or bronchiectasis. The Flutter® device, autogenic drainage, and positive expiratory pressure are simple devices or maneuvers that can be learned by most patients. In contrast, intrapulmonary percussive ventilation or high-frequency chest wall compression, e.g., with the Vest Airway Clearance System are more complex devices.

The use of high-frequency chest wall compression and intrapulmonary percussive ventilation devices in other chronic pulmonary diseases, such as COPD, remains investigational due to insufficient evidence on the impact of treatment on health outcomes.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

# Oscillatory Devices for the Treatment of Respiratory Conditions

Applicable codes: A7025, A7026, E0483, E0484, E0481, S8185

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual - 11/1/97

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 5/2001

Windows on Medical Technology October 2000 Issue No. 40.

BCBSA Medical Policy Reference Manual 7/12/02, 1.01.05

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 04/01/2005

Region C DMERC Supplier Manual. High Frequency Chest Wall Oscillation Devices (April 2005).

Retrieved 4/2/07 from [http://www.palmettogba.com/palmetto/providers\\_a.nsf/Attachments/85256D57005BA23B85257013004989A0/\\$FILE/Spring2005ManualRevised.pdf](http://www.palmettogba.com/palmetto/providers_a.nsf/Attachments/85256D57005BA23B85257013004989A0/$FILE/Spring2005ManualRevised.pdf)

Institute for Clinical Systems Improvement (ICSI). Technology Assessment Report on High Frequency Chest Compression Devices for Cystic Fibrosis Patients. Technology Assessment #5 (April 2005).

Retrieved 4/2/07 from [http://www.icsi.org/technology\\_assessment\\_reports\\_-\\_inactive/ta\\_high\\_frequency\\_chest\\_compression\\_devices\\_for\\_cystic\\_fibrosis\\_patients\\_-\\_inactivated\\_04\\_2005.html](http://www.icsi.org/technology_assessment_reports_-_inactive/ta_high_frequency_chest_compression_devices_for_cystic_fibrosis_patients_-_inactivated_04_2005.html)

McCool DF, Rosen MJ. (January 2006). Nonpharmacologic Airway Clearance Therapies: ACCP Evidence-Based Clinical Practice Guidelines. *Chest* 2006; 129; 250-259. Retrieved 3/22/07 from [http://chestjournals.org/cgi/content/abstract/129/1\\_suppl/250](http://chestjournals.org/cgi/content/abstract/129/1_suppl/250)

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 12/11/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 3/11/2010

Specialty Matched Consultant Advisory Panel review - 3/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 2/10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 2/9/12

Specialty Matched Consultant Advisory Panel review- 3/2012

## Policy Implementation/Update Information

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3/24/98 Original policy issued.

8/24/98 Information based on BCBSA's policy is in quotes. Flutter devices used in the administration of medication for Cystic Fibrosis may be considered medically necessary.

8/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.

12/99 Medical Policy Advisory Group

4/01 System changes.

5/01 Specialty Matched Consultant Advisory Panel review (5/2001). Changed wording in policy section to state, "BCBSNC does not provide coverage for Oscillatory Devices for the Treatment of Cystic Fibrosis. It is considered not medically necessary. BCBSNC does not

# Oscillatory Devices for the Treatment of Respiratory Conditions

- provide coverage for Oscillatory Devices used as an adjunct to chest physical therapy for Treatment of Cystic Fibrosis or for use in any disease other than Cystic Fibrosis. It is considered investigational. BCBSNC does not provide coverage for investigational services." Policy name changed from Oscillatory Devices for the Treatment of Cystic Fibrosis to Oscillatory Devices for the Treatment of Respiratory Conditions. E0457 removed from applicable codes.
- 6/01 In review of 5/01, the wording in the policy section states, "BCBSNC does not provide coverage for Oscillatory Devices used as an alternative to chest physical therapy for the Treatment of Cystic Fibrosis. It is considered not medically necessary. BCBSNC does not provide coverage for Oscillatory Devices used as an adjunct to chest physical therapy for Treatment of Cystic Fibrosis or for use in any disease other than Cystic Fibrosis. It is considered investigational. BCBSNC does not provide coverage for investigational services." The underlined portion was left out of the 5/01 Policy Implementation/Update Information section of the policy.
- 4/02 Format changes.
- 5/03 Specialty Matched Consultant Advisory Panel review 5/2003. No change in criteria. Code S8200 removed from policy as it was deleted from HCPCS on 12/31/2002. New HCPCS codes E0483 and E0484 added to policy. Reaffirm policy.
- 5/04 Benefits Application and Billing/Coding section updated for consistency.
- 8/12/04 Codes A7025 and A7026 added to Billing/Coding section.
- 7/7/05 Specialty Matched Consultant Advisory Panel review on 5/26/2005. DME0200 added as key word. Policy restructured to reflect coverage for High Frequency Chest Wall Oscillation Devices for patients with cystic fibrosis that meet specified medical criteria. Description revised to describe cystic fibrosis disease process and indicates several types of oscillatory devices that are used. Criteria for coverage outlined in Policy statement as well as Covered section. Likewise, reasons for noncoverage were outlined in not covered section. Warranty information included in Policy Guidelines section. Reference added. Discussed at June 13, 2005 MPOC meeting. Codes E0481 and S8185 added to Billing/Coding section. E0484, E0481, and S8185 are codes for devices that are still considered investigational.
- 12/11/06 Added a statement to Item #4 in the section "When Oscillatory Devices are covered" that reads: Appropriate usage is defined as daily treatment sessions for an absolute minimum of 15 minutes per session.
- 7/2/07 References updated. Specialty Matched Consultant Advisory Panel review 5/25/07. No changes to policy coverage criteria. (adn)
- 6/22/09 Specific devices added to Description section. Policy statement revised to indicate that intrapulmonary percussive devices are considered investigational and that flutter devices may be medically necessary when the medical criteria for coverage have been met. Criteria in the When Covered section was deleted and replaced with the following: High-frequency chest wall compression devices may be considered medically necessary: as an alternative to chest physical therapy for airway clearance in patients with cystic fibrosis or chronic bronchiectasis (as determined by specific criteria, including chest CT scan), AND when standard chest physiotherapy has failed (i.e., the patient has frequent severe exacerbations or respiratory distress involving inability to clear mucus despite percussion and postural drainage, OR when standard chest physiotherapy cannot be performed (e.g., no caregiver is available to perform percussion and postural drainage). Use of the flutter valve or Acapella device may be considered medically necessary in patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and have recurrent disease exacerbations. Statement in the When Not Covered section deleted and replaced with the following: Intrapulmonary percussive ventilation devices are considered investigational in the treatment of patients with chronic pulmonary diseases including cystic fibrosis and bronchiectasis. High-frequency chest wall compression devices are considered not medically

# Oscillatory Devices for the Treatment of Respiratory Conditions

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 these situations. Other applications of high-frequency chest wall compression devices, including, but not limited to, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as COPD, are considered investigational. The following statement was added to the Policy Guidelines: For the purposes of this policy, chronic bronchiectasis is defined by daily productive cough for at least 6 continuous months or more than two exacerbations per year requiring antibiotic therapy and confirmed by high resolution or spiral chest CT scan. Information on specific devices moved from Policy Guidelines to the Description section. Specialty Matched Consultant Advisory Panel review 5/13/09.

- 6/8/10 Description section extensively revised. The following Policy statement was deleted: “BCBSNC does not provide coverage for intrapulmonary percussive ventilation devices.” The section titled **When Oscillatory Devices for the Treatment of Respiratory Conditions Are Covered** was replaced with the following: Use of the FLUTTER® valve or Acapella 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 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 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 the FLUTTER device), or valid reasons why standard chest physiotherapy cannot be performed, such as inability of the caregiver to perform it. The section titled **When Oscillatory Devices for the Treatment of Respiratory Conditions Are Not Covered** was replaced with the following: High-frequency chest wall compression 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 COPD, are considered investigational. (adn)
- 4/12/11 Specialty Matched Consultant Advisory Panel review 3/2011. Minor formatting changes made. “Policy Guidelines” updated. No change to policy intent. (btw)
- 5/10/11 References updated. (btw)
- 3/30/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. Updated Policy Guidelines section. No change to policy statement. (lpr)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.