

Corporate Medical Policy

Oscillatory Devices for the Treatment of Respiratory Conditions

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Description of Procedure or Service

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 disease (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, HFCWO (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

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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 chronic obstructive pulmonary disease (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:

- Flutter® Mucus Clearance Device in 1994. The Flutter device is currently marketed in the United States by Axcan.
- Vest™ Airway Clearance System (Hill-Rom) 1998.
- 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
- AerobiKA oscillating PEP device (Trudell Medical, London, ON) in 2013.
- The Vibralung Acoustical Percussor May 2014.
- The Monarch™ Airway Clearance System (Hill-Rom) 2017.

*****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

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 an oscillatory expiratory pressure device when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

Benefits Application

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.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Oscillatory Devices for the Treatment of Respiratory Conditions are covered

Use of an oscillatory positive expiratory pressure (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 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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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 that 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 (COPD), or respiratory conditions associated with neuromuscular disorders are considered **investigational**.

Policy Guidelines

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 Chest PT is unavailable, ineffective, or not tolerated. There should be documented failure of standard treatments (chest physiotherapy 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.
- 4) A documented successful 4 month trial period using the high frequency chest wall oscillation device is required to determine patient and family compliance. This includes written confirmation that the patient has demonstrated sufficient and appropriate usage of the device during the trial period. Appropriate usage is defined as daily treatment sessions for an absolute minimum of 15 minutes per session.
- 5) The device is prescribed by either a pulmonologist or a cystic fibrosis clinic.

For individuals who have CF 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. 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 another recognized airway clearance techniques; some were published only as abstracts. Study findings could not be pooled due to heterogeneity in study design and outcome measures. The systematic review concluded that additional RCTs are needed that are adequately powered and have long-term follow-up. 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 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.

Clinical input, obtained in 2008, was supportive of the use of oscillatory devices to treat patients with CF 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 or is unavailable, or is not tolerated by the patient.

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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, lack of 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.

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

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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 94669, A7025, A7026, E0481, E0483, E0484, 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

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/

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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

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 - 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 -3/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 2/14/13

Specialty Matched Consultant Advisory Panel 3/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 2/13/14

Specialty Matched Consultant Advisory Panel 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 2/12/15

Specialty Matched Consultant Advisory Panel 3/2015

Specialty Matched Consultant Advisory Panel 3/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 6/16/16

Specialty Matched Consultant Advisory Panel 3/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 6/8/17

Senior Medical Director review 6/2017

[Int J Chron Obstruct Pulmon Dis.](#) 2017 Oct 19;12:3065-3073. doi: 10.2147/COPD.S143334. eCollection 2017.

Specialty Matched Consultant Advisory Panel 3/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.15, 6/14/18

Medical Director review 8/2018

Policy Implementation/Update Information

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 provide coverage for Oscillatory Devices used as an adjunct to chest physical therapy for

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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

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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 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)
- 4/16/13 Specialty Matched Consultant Advisory Panel review meeting 3/20/13. Reference added. No change to policy statement. (lpr)
- 12/31/13 Added CPT code 94669 to Billing/Coding section for 2014 code update. (lpr)
- 5/13/14 Description and Policy Guidelines sections updated. Under “When Covered” section, Flutter and/or Acapella changed to oscillatory positive expiratory pressure device. Under Policy Guidelines section, standard chest physiotherapy treatment changed to standard

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- treatment. Reference updated. Specialty matched consultant advisory panel review meeting 4/30/2014. (lpr)
- 10/28/14 Added the following statement to the Benefits Application section: “The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.” (mco)
- 4/28/15 Updated Regulatory Status. Specialty matched consultant advisory panel review 3/25/2015. Reference added. No change to policy statement. (lpr)
- 4/29/16 Specialty Matched Consultant Advisory Panel review 3/30/2016. Changed the word “disorder” to “disease” in reference to COPD throughout the policy. No change to policy statement. (lpr)
- 7/26/16 Policy Guidelines section updated. Reference added. No change to policy statement. (lpr)
- 4/28/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. No change to policy statement. (lpr)
- 7/28/17 Under “When Not Covered” section, 1) removed the following not medically necessary statement: “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,” 2) “patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above” and “or respiratory conditions associated with neuromuscular disorders” added to investigational statement. Senior Medical Director review 6/2017. Reference added. (lpr)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. Reference added. (lpr)
- 7/27/18 Updated Regulatory Status section for Oscillatory devices. No change to policy statement. Reference added. (lpr)
- 8/24/18 Under Policy Guidelines section #4, added definitive trial period for clarification. Medical Director review 8/2018. No change to policy statement. (lpr)

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.