



Corporate Medical Policy

Oscillatory Devices for the Treatment of Respiratory Conditions

File Name: oscillatory_devices_for_treatment_of_respiratory_conditions
Policy Number: DME0200
Origination: 3/1998
Last Review: 5/2009
Next Review: 5/2011

Description of Procedure or Service

In cystic fibrosis, excessive tenacious secretions necessitate routine chest physiotherapy (CPT) to prevent airway obstruction leading to secondary infection, the principal cause of morbidity and mortality. At home, manual CPT is administered to the patient by a trained adult one to three times a day for 20-30 minutes per session. Manual CPT requires assistance by another person, thereby making independent living or the lack of a competent caregiver a barrier to achieving the standard of care in some persons with cystic fibrosis.

There are a number of alternative methods available to support good bronchial hygiene in persons with chronic pulmonary conditions that are unable to comply with a prescribed regimen of pulmonary therapy. Oscillatory devices have been investigated as an alternative to conventional chest physical therapy. Each of these devices enables the patient or the caretaker to help clear the airway.

Oscillatory Devices

The High frequency chest wall oscillation (HFCWO) device provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Tubing connects the vest to the air-pulse generator. Pressure pulses are created that cause the vest to inflate and deflate against the chest wall, causing high-frequency chest wall vibration and movement of the secretions in the lungs. There are two companies that manufacture these vests: The Vest® airway clearance system by Advanced Respiratory (subsidiary of Hill-Rom) and the Medpulse SmartVest® by ElectroMed.

The Intrapulmonary Percussive Ventilation (IPV) device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol through a nebulizer. IPV patients breathe through a mouthpiece, then cough to clear the loosened secretions. The Intrapulmonary Percussionator Ventilator® by Percussionair Corp and The Percussive NEB™ by Vortran Medical Technology are two such devices.

The Flutter device is another oscillatory device that has been used in patients with cystic fibrosis. It is a small pipe-shaped, 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 airway and loosening of the mucus results. Two devices are: Acapella® by DHD Healthcare and the Flutter® by Axcan Pharma.

Policy

BCBSNC **will** provide coverage for high frequency chest wall oscillation when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

BCBSNC **does not** provide coverage for intrapulmonary percussive ventilation devices. They are con-

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sidered investigational and BCBSNC does not cover investigational devices.

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

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Oscillatory Devices for the Treatment of Cystic Fibrosis are covered

- A. High-frequency chest wall compression devices may be considered medically necessary:
 - 1. 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
 - 2. 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
 - 3. when standard chest physiotherapy cannot be performed (e.g., no caregiver is available to perform percussion and postural drainage).
- B. 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.

When Oscillatory Devices for the Treatment of Cystic Fibrosis are not covered

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 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.

Policy Guidelines

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

- 1. The device is used for a patient with cystic fibrosis or chronic bronchiectasis who requires effective chest physiotherapy when conventional manual CPT is unavailable, ineffective, or not tolerated. Patients benefitting most from the device are adolescents and older patients due to lifestyle issues in which manual conventional CPT is essentially unavailable. Patients should demonstrate high motivation and compliance with use of the device.

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2. 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.
3. The device is prescribed for patients who actually do have bronchopulmonary secretions to mobilize. It should not be used prophylactically to prevent onset of respiratory symptoms.
4. The patient has high frequency chest wall oscillation prescribed by either a pulmonologist or a cystic fibrosis clinic.
5. Patient has a documented successful 4 month trial period using the high frequency chest wall oscillation device. 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.
6. Therapy with the device is closely supervised and monitored by the prescribing physician on a monthly basis to ensure compliance and continued efficacy. Monthly symptom assessment results and treatment compliance analyses are closely monitored by the prescribing physician.
7. The patient demonstrates to the prescribing physician that the device has proven efficacy and that the patient will be compliant and accepting of its use in the home. Documentation of efficacy is critical because patients with severe small airway obstruction and debilitation may be unable to cough effectively, regardless of the mode of CPT.

After the initial authorization and purchase of the vest system, BCBSNC members will receive all replacements needed to operate the HFCWO system. All replacement costs are included in the payment of the original HFCWO system. This includes, but is not limited to refit vests, hoses, and the generator.

A lifetime warranty is included with the purchase of The Vest® airway clearance system and the Medpulse SmartVest®.

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: 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

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

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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

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

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 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.

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- 7/7/2005 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 non-coverage 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 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.

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.