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Subject: Oscillatory Devices Used in the Home for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

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 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 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 (eg, the Vest Airway Clearance System) are passive oscillatory devices designed to provide airway clearance without 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.

All of these techniques may be alternatives to daily percussion and postural drainage in patients with cystic fibrosis, also known as chest physical therapy. Oscillatory devices can also be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as patients with bronchiectasis or a neuromuscular disorder who have impaired cough clearance.

Summary and Analysis of Evidence: The evidence for the use of percussors, also known as chest physiotherapy or chest percussion, in mobilizing respiratory tract secretions in patients with COPD, chronic bronchitis, and emphysema includes studies, controlled trials, and systematic reviews. The evidence indicates that percussors can be an effective adjunctive therapy in improving lung function, reducing symptoms, and enhancing mucus clearance in these patients. Wheately et al (2018) evaluated the safety and effectiveness of the Vibralung Acoustical Percussor, an airway clearance therapy (ACT) that uses intrapulmonary sound waves and positive expiratory pressure to help clear mucus from lungs. The study concluded, “This study demonstrates that the Vibralung, an acoustic ACT [airway clearance therapy] device that couples sound waves directly to the tracheobronchial airways for the purpose of loosening and mobilizing mucus, is well tolerated in individuals with CF with or without a pulmonary exacerbation and does not induce lung damage that could be detected by conventional pulmonary function tests.” The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Alghamdi et al (2023) investigated the effectiveness of oscillatory positive expiratory pressure (OPEP) devices in patients with COPD who produced sputum regularly. The study found that using an OPEP device (Acapella) for 3 months improved: cough-related quality of life; fatigue; generic quality of life; and reduced cough frequency by 60 coughs per 24 hours. The study concluded that “Regular use of an Acapella device improves symptoms and quality of life in people with COPD who produce sputum daily or most days.” Volsko et al (2003) compared the performance of the Flutter and the Acapella. The study concluded, “Acapella and Flutter have similar performance characteristics. Acapella's performance is not gravity-dependent (ie, dependent on device orientation) and may be easier to use for some patients, particularly at low expiratory flows.” The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Volara System Oscillation and Lung Expansion (OLE) therapy is a non-invasive respiratory therapy that utilizes a device to provide oscillatory positive expiratory pressure (OPEP) to help improve lung function and clear mucus. The MetaNeb System is a portable, battery-powered device that provides continuous high-frequency oscillation (CHFO) therapy to help clear mucus and improve lung function. There is a lack of evidence supporting the effectiveness of the devices including limited clinical trials, small sample size and/or short duration studies. There is no standardized protocol for OLE therapy or for CHFO therapy in the home setting. Large, well-designed randomized control trials with standardized protocols and longer study durations are needed to establish the efficacy and effectiveness of OLE therapy and CHFO therapy in the home setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

High frequency chest wall compression devices **meet the definition of medical necessity** when criteria 1, 2 or 3, and 4 are met:

1. The member has a diagnosis of cystic fibrosis; **OR**
2. The member has a diagnosis of bronchiectasis confirmed by a high resolution, spiral, or standard CT scan and is characterized by **ONE** of the following:
    - Daily productive cough for at least 6 continuous month
    - Frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy

OR

3. The member has a neuromuscular disorder which has resulted in clinically documented respiratory muscle weakness and/or ineffective cough. Examples of neuromuscular disorders include,but are not limited to the following:
    - Post-polio syndrome
    - Acid maltase deficiency
    - Anterior horn cell disease
    - Paraplegia, Quadriplegia
    - Muscular dystrophy
    - Myotonic disorders
    - Other myopathies.

AND

4. There is documentation in the member's medical record that standard chest physiotherapy (any of the following: postural drainage, daily percussion, turning deep breathing exercises) to adequately mobilize secretions have failed (e.g., physician history and physical, progress notes, respiratory therapy progress notes) or is not available or tolerated.

Continued use of rented Oscillatory High-Frequency Chest Wall Compression Device:

Continued use **meets the definition of medical necessity** with documentation supporting continued need based on the initial criteria.

The Flutter® valve and Acapella® device **meets the definition of medical necessity** when used on a daily basis for members with hypersecretory lung disorders who are required to do daily pulmonary drainage or compression physiotherapy to help loosen secretions from the respiratory tract (e.g., bronchial drainage).

Percussors used for mobilizing respiratory tract secretions in members with chronic obstructive lung disease, chronic bronchitis, or emphysema, **meet the definition of medical necessity** when the member or operator of the powered percussor receives appropriate training by a physician or therapist, and there is no competent caregiver available to administer manual therapy.

The Vibralung Acoustical Percussor **meets the definition of medical necessity** for members who meet the following indications:

- the member meets the criteria for a high frequency chest wall compression device; **AND**
- is unable to use a high frequency chest wall compression device (i.e., burns, chest trauma).

Other applications of oscillatory devices are considered **experimental or investigational.** There is insufficient published scientific evidence to permit conclusions regarding the effect on health outcomes, specifically for use as an adjunct to chest physical therapy or for conditions other than cystic fibrosis or bronchiectasis.

The Volara™ System Oscillation & Lung Expansion (OLE) therapy device (E0469) is considered **experimental or investigational**. There is insufficient published clinical data to permit conclusions regarding the effect on health outcomes.

The MetaNeb™ System (E1399) is considered **experimental or investigational**. There is insufficient published clinical data to permit conclusions regarding the effect on health outcomes.

Intrapulmonary percussive ventilation (IPV) is considered **experimental or investigational.** There is insufficient published clinical data to permit conclusions regarding the effect on health outcomes.

BILLING/CODING INFORMATION:

HCPCS Coding:

A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter) (**Investigational**)
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (**Investigational**)
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussive ventilation system and related accessories (**Investigational**)
E0483	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each
E0484	Oscillatory positive expiratory pressure device, nonelectric, any type, each
S8185	Flutter device

LOINC Codes:

The following information may be required documentation to support medical necessity: Treating physician history and physical; treatment notes including established diagnosis; respiratory therapy treatment notes and progress notes.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative

Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note or treatment notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Respiratory therapy treatment plan	27726-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Respiratory therapy treatment, progress	27721-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Replacement supplies (A7025 and A7026) used with member owned equipment are reimbursable if the member meets the criteria listed above for the base device (E0483).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Intrapulmonary Percussive Ventilator (240.5) located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date: Intrapulmonary Percussive Ventilation System (L33786), High Frequency Chest Wall Oscillation Devices (L33785) located at cgsmedicare.com.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Bronchiectasis: dilation of the bronchi due to infection or chronic conditions, causing decreased lung capacity and recurrent infections of lungs.

Chest percussion: the act or technique of massage consisting of the striking of the back with light rapid blows to loosen secretions in the lungs.

Cystic fibrosis (CF): a genetic condition that results in excessive and difficult-to-clear mucous secretions in the lungs, leading to airway obstruction, infection, hypoxemia, and bronchiectasis; requires routine maintenance chest physical therapy on a daily basis; symptoms are eventually fatal.

Hypersecretory: The production of excessive amounts of mucus. Hypersecretion occurs during infections in an attempt to rid the body of the microorganisms causing the infection.

Oscillation: the action or state of oscillating; something that moves or travels back and forth between two points.

Postural drainage: drainage of the lungs by placing the patient in an inverted position so that fluids are drawn by gravity toward the trachea.

RELATED GUIDELINES:

None applicable.

OTHER:

None Applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/25/26.

GUIDELINE UPDATE INFORMATION:

09/01/01	Medical Coverage Guideline Reformatted.
01/01/02	HCPCS coding changes.
10/24/02	Reviewed for investigational; some information revised using BCA policy (MPCC).
12/15/02	Changed guideline name to oscillatory devices, and added flutter device in the guideline title. Added coverage criteria for children with cystic fibrosis. The coverage criteria are based on coverage of other plans (Care First Blue Minnesota, California).
09/15/03	Reviewed; removed references to age requirement.
06/15/04	Unscheduled review; revised to include Program Exception for Medicare & More.
06/15/05	Scheduled review and revision, consisting of inclusion of an additional covered indication.
07/15/06	Scheduled review; added DME code E0480; no change in coverage statement.
07/15/07	Scheduled review; added position statement regarding percussors; added reimbursement statement for associated supplies; reformatted guidelines; updated references.
07/15/08	Annual review; no change in position statement; references updated.
07/15/09	Scheduled review; position statement revised with additional criteria; updated ICD-9 diagnosis coding; added Program Exception for Medicare Advantage; updated references; formatting changes.
12/15/10	Revisions: related ICD-10 codes added, formatting changes.
02/15/11	Review; Position Statement revised; references updated; formatting changes.
09/15/11	Revision; formatting changes.
06/15/13	Revision: Title revised; Description section updated; Program Exceptions section updated; additional brand names added.
04/15/15	Revision; Position statement, description, and references updated; formatting changes.
11/01/15	Revision: ICD-9 Codes deleted.
10/01/16	Revision; coding section updated.
05/15/18	Revision; description, position statements, program exception, and references updated; formatting changes.
01/01/19	Annual CPT/HCPCS coding update. Revised code E0483.
12/15/20	Review; position statements and references updated.
04/15/22	Review: MetaNeb investigational position statement added; policy title and references updated.
10/01/22	Quarterly CPT/HCPCS coding update. Code E0483 revised.
08/15/24	Review: Position statements maintained and references updated.
10/01/24	Quarterly CPT/HCPCS coding update. Code E0469 added.
10/15/24	Coding section updated.
10/15/25	Annual review; Position statements maintained; description and references updated.