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

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 04/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider high-frequency chest wall compression devices in individuals with cystic fibrosis (CF) or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography scan) when standard chest physical therapy has failed OR standard chest physical therapy is unavailable or not tolerated.to be **eligible for coverage.****

Note:
In considering the chest wall compression there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments, ie, the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physical therapy and, if appropriate, use of an oscillatory PEP device) or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.

Based on review of available data, the Company may consider the use of an oscillatory positive expiratory pressure (PEP) device (such as Flutter® Mucous Clearance system and Acapella® Vibratory PEP Therapy System)‡ in individuals with hyper-secretory lung disease (i.e., production of excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations to be **eligible for coverage.****

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Note:
For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months or more than 2 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 individuals' responses to the various types of devices can be variable; the types of devices should be considered as alternative, and not equivalent, devices.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other applications of high-frequency chest wall compression devices, including but not limited to, their use in individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease (COPD) or respiratory conditions associated with neuromuscular disorders, to be **investigational.***

Based on review of available data, the Company considers intrapulmonary percussive ventilation devices (such as the Percussionaire® devices and the Volara™ System)‡ to be **investigational*** for all indications, including but not limited to, cystic fibrosis, bronchiectasis, COPD, and neuromuscular conditions associated with retained airway secretions or atelectasis.

Based on review of available data, the Company considers the use of an oscillatory positive expiratory pressure (PEP) device when above criteria are not met to be **investigational.***

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Policy Guidelines

For this policy, chronic diffuse bronchiectasis is defined by a daily productive cough for at least 6 continuous months or exacerbations more than 2 times per year 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 for whom, due to lifestyle factors, manual percussion and postural drainage may not be available.

A trial period may also be helpful because individuals' responses to different types of devices can vary; the types of devices should be considered as alternative, not equivalent, devices.

Background/Overview

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.

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Intrapulmonary Percussive Ventilation (IPV) devices are a type of pneumatic, oscillating pressure breathing devices that are designed to loosen mucus by internally percussing the airways using high frequency, high flow, and low-pressure bursts of gas delivered via a mouthpiece, mask or endotracheal tube. The user actuates a thumb control to trigger 15 to 25 high frequency pulses of air during inspiration and releases the control to allow for passive exhalation. Airway pressures oscillate between 5 and 35 cm H_2O, and the walls of the airways vibrate synchronously with these oscillations. A Venturi type system, powered by compressed gas, generates the oscillations at a rate of 100 to 300 cycles per minute. Pressures, inspiratory time, and delivery rates are adjustable. Additionally, some devices are designed to deliver aerosolized medications, and other pulmonary therapies such as bi-level positive airway pressure (BiPAP) and continuous positive expiratory pressure (CPEP). The clinical utility of the device is purportedly to loosen retained secretions by means of these airway oscillations, and it has been investigated in the treatment of individuals suffering from secretion retention (particularly that associated with cystic fibrosis), as well as atelectasis.

Intrapulmonary percussive ventilation devices have been investigated as an alternative to standard chest physiotherapy (CPT) and percussion and postural drainage (P/PD) with or without manual vibration, with most studies having been in subjects with a diagnosis of cystic fibrosis. Multiple IPV devices have been cleared by the FDA for similar indications, including the mobilization of endobronchial 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. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, often a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who 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. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

This evidence review addresses the outpatient use of oscillatory devices. This review does not address inpatient device use (eg, in the immediate postsurgical period).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, including those listed in Table 1.

Table 1. Select Oscillatory Devices Cleared by the Food and Drug Administration

Device	Manufacturer	Clearance Date
Flutter Mucus Clearance Device	Axcan Scandipharm (for marketing in the United States)	1994
Vest Airway Clearance System	Hill-Rom	1998
Acapella device	DHD Healthcare	1999
RC Cornet®‡ Mucus Clearing Device	PARI Respiratory Equipment	1999
inCourage®‡ System	RespirTech	2005
Lung Flute®‡	Medical Acoustics LLC	2006
Smartvest Airway Clearance System	Electromed	2013
AerobiKA®‡ oscillating PEP device	Trudell Medical	2013
Vibralung® ‡Acoustical Percussor	Westmed	2014
The Vest Airway Clearance System	Hill-Rom	2015
iPEP®‡ system including PocketPEP®‡ and vPEP®‡	D R Burton Healthcare	2016
The Monarch™‡Airway Clearance System	Hill-Rom	2017
Pulsehaler™‡	Respinova	2021

PEP: positive expiratory pressure.
U.S. Food and Drug Administration product codes: BYI, BYT.

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There are several devices with IPV capability currently available on the market, including the Volara™‡ System (cleared by the FDA in 2020; Hill-Rom Services, Inc., Chicago, IL), and multiple Percussionaire Corporation TRUE-IPV®‡ products (Sandpoint, ID) including the Bronchotron®‡ Transport, Impulsator®‡, IPV®‡ -1C, IPV®‡ -2C, Phasitron®‡, Travel Air®‡, TXP®‡ 5, and the VDR®‡ -4.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Oscillatory devices are 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. Respiratory therapists and other providers may also use oscillatory devices for other respiratory conditions such as diffuse bronchiectasis, chronic obstructive pulmonary disease (COPD), and respiratory conditions associated with neuromuscular disorders.

Summary of Evidence

For individuals who have cystic fibrosis 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. The RCTs reported mixed findings and limitations such as small sample sizes and large dropout rates. A systematic review identified 39 RCTs comparing oscillatory devices with other recognized airway clearance techniques; some were published only as abstracts. Reviewers could not pool findings due to heterogeneity in study designs and outcome measures and concluded that additional adequately powered RCTs with long-term follow-up would be needed to make conclusions about oscillatory devices for cystic fibrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 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 that the technology results in an improvement in the net health outcome.

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 reported mixed findings and did not clearly support the use of oscillatory devices in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 statistically significant differences. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvements 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 that the technology results in an improvement in the net health outcome.

For individuals who receive IPV devices there is limited published data by which to establish the effectiveness for airway clearance. In the available studies, the numbers of subjects have been small, with variable study populations and treatment settings (in-hospital versus outpatient). Outcome measures differed among the studies, including factors such as sputum volume, sputum viscosity, pulmonary function data or radiographic changes, depending on the study design and study population. Studies did not compare IPV to different alternative airway clearance modalities (e.g., Flutter valve, and/or high frequency chest compression [HFCC] device, chest physiotherapy and percussion and postural drainage). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
2008 Input
Clinical input obtained in 2008 supported the use of oscillatory devices to treat patients with cystic fibrosis 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, is unavailable, or is not tolerated by the patient.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers while this policy was under review in 2008. Input indicated the available studies demonstrated that these oscillatory devices are comparable with chest physical therapy for cystic fibrosis and bronchiectasis. 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. Input did not support the use of oscillatory devices for treatment of chronic obstructive pulmonary disease.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians
In 2006, the guidelines from the American College of Chest Physicians recommended (level of evidence: low) that, in patients with cystic fibrosis, devices designed to oscillate gas in the airway,

either directly or by compressing the chest wall, can be considered as an alternative to chest physical therapy.

A 2018 document from the American College of Chest Physicians recommends that airway clearance strategies in children and adults with productive cough due to bronchiectasis related to any cause be individualized to the patient (ungraded, consensus statement).

Cystic Fibrosis Foundation
In 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. The Foundation recommended airway clearance therapies for all patients with cystic fibrosis but stated that no therapy had been demonstrated to be superior to others (level of evidence: fair; net benefit: moderate; grade of recommendation: B).

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04271969	Clinical Effectiveness of High Frequency Chest Wall Oscillation (HFCWO) In A Bronchiectasis Population	100	Jul 2023
NCT05548036	A Feasibility Randomized Control Trial (RCT) of Aerobika TM Verses Active Cycle of	120	Apr 2024

	Breathing Technique (ACBT) in People with Chronic Obstructive Pulmonary Disease (COPD) (TIPTOP)		
Completed			
NCT05034900	Does Addition of Oscillatory Positive Expiratory Pressure (OPEP) Device to a Chest Physiotherapy Program Provide Further Health Benefits in Children with Bronchiectasis?	42	Sept 2022

NCT: national clinical trial.

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Policy History

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12/19/2002	Medical Policy Committee review
03/24/2003	Managed Care Advisory Council approval
12/16/2003	Medical Director review
01/27/2004	Managed Care Advisory Council approval
03/08/2004	Medical Director review
03/16/2004	Medical Policy Committee review. Policy revision addresses investigation status of the use of oscillatory devices for the treatment outside of cystic fibrosis.
03/29/2004	Managed Care Advisory Council approval
03/01/2005	Medical Director review
03/15/2005	Medical Policy Committee review
04/04/2005	Managed Care Advisory Council approval
04/05/2006	Medical Director review
04/19/2006	Medical Policy Committee approval. Format Revisions: FDA/Governmental Regulations, Rationale/Source
03/14/2007	Medical Director review
03/21/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2008	Medical Director review
07/16/2008	Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2008	Medical Director review
07/22/2009	Medical Policy Committee approval. Extensively revised the coverage section.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/08/2011	Medical Policy Committee review

12/21/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Added IPV to policy statements, replaced Flutter and Acapella with "oscillatory PEP devices" in policy statements. Updated rationale and references.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Patients with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, "disorders" changed to "conditions".
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. 'Not medically necessary' statement removed and "patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above" added to the investigational statement.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/02/2021	Medical Policy Committee review

09/08/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022 Medical Policy Committee review
09/14/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. Added examples of oscillatory PEP devices. Added a new investigational statement. "Based on review of available data, the Company considers intrapulmonary percussive ventilation devices (such as the Percussionaire® devices and the Volara™ System)‡ to be investigational* for all indications, including but not limited to, cystic fibrosis, bronchiectasis, COPD, and neuromuscular conditions associated with retained airway secretions or atelectasis."
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. Added investigational statement for oscillatory positive expiratory pressure (PEP) device to deny when criteria not met.
03/28/2024 Coding update
09/18/2024 Coding update
Next Scheduled Review Date: 03/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	A7025, A7026, E0468, E0480, E0481, E0483, E0484, E1399 Add codes effective 10/01/2024: A7021, E0469
ICD-10 Diagnosis	E84.0-E84.9, J47.0-J47.9, J67.0

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);

2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.