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MEDICAL POLICY – 1.01.539

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

BCBSA Ref. Policy:	1.01.15	
Effective Date:	Nov. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 13, 2025	None
Replaces:	1.01.15	

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Introduction

Certain diseases like cystic fibrosis can cause a lot of sticky mucus in the lungs. Clearing the mucus helps prevent infection and inflammation. Chest physiotherapy, also called manual chest physical therapy, is the standard way of clearing airways. Devices that vibrate, called oscillators, may also be used in certain situations. An oscillating positive expiratory pressure device (PEP) creates vibrations as a person breathes into a handheld device. A high-frequency chest wall oscillation device uses an inflatable vest attached to a machine. The device causes the vest to inflate and deflate very fast to loosen the mucus. An intrapulmonary percussive ventilator gives fast bursts of air through a mouthpiece and into the airway. This allows the mucus to be coughed out or suctioned. This policy describes when specific oscillatory devices may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Medical Necessity
Positive expiratory pressure device (PEP)	**Use of an oscillatory positive expiratory pressure (OPEP) device may be considered medically necessary in individuals with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing their secretions and have recurrent disease exacerbations.**
High-frequency chest wall compression and IPV devices	**High-frequency chest wall compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered medically necessary when the following criteria are met (see Additional Guidelines below):** • The individual has a diagnosis of cystic fibrosis **OR** • Has a diagnosis of chronic diffuse bronchiectasis confirmed by high-resolution or spiral chest CT scan and has **ONE** of the following: o Daily productive cough for at least 6 continuous months; **or** o Exacerbations more than 2 times per year requiring antibiotic therapy **AND** • Standard chest physical therapy has failed; **or** • Standard chest physical therapy is unavailable or not tolerated **Other applications of high-frequency chest wall compression devices and IPV devices, including, but not limited to, their use in individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above are considered not medically necessary.** **The use of high frequency chest wall compression devices and IPV devices as an adjunct to chest physical therapy are considered not medically necessary.**
Use of high frequency chest wall compression and IPV devices for other conditions	**The use of high frequency chest wall compression devices and IPV devices in other lung diseases such as chronic obstructive pulmonary disease (COPD) or respiratory conditions associated with neuromuscular disorders are considered not medically necessary.**

Device	Investigational
Other devices	**Oscillation and lung expansion (OLE) devices for the treatment of respiratory conditions are considered investigational (e.g., the Volara System, BiWaze Clear System, and MetaNeb4 System)**

Additional Guidelines

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 individual has frequent severe exacerbations of respiratory distress involving the inability to clear mucus despite standard treatment [chest physical therapy and, if appropriate, use of an OPEP device] or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it).

For the chest wall compression devices, a trial period to determine individual 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.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- History and physical with relevant diagnoses or conditions.
- Documentation that individuals have difficulty clearing their secretions and have recurrent disease exacerbations
- For high-frequency chest wall compression devices or intrapulmonary percussive ventilation devices, in addition to the above also include the following:
  - Request is for diagnosis of cystic fibrosis or
  - Chronic diffuse bronchiectasis, and the diagnosis is confirmed by high-resolution or spiral chest CT scan, and the individual has one of the following:

Documentation Requirements

- Daily productive cough for at least 6 continuous months or
- Exacerbations more than two times per year requiring antibiotic therapy
  - Documented failure of standard chest physical therapy OR standard chest physical therapy cannot be tolerated or is unavailable

Coding

Code	Description
HCPCS	
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter) (Used to report Volara)
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 (used to report Volara)
E0481	Intrapulmonary percussive ventilation system and related accessories
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, non-electric, any type, each
E1399	Durable medical equipment, miscellaneous (used to report BiWaze Clear System, and MetaNeb4 System)

Related Information

Benefit Application

Oscillatory devices such as the Flutter device, the Vest Airway Clearance System, and Percussionaire IPV device have been primarily investigated as an **alternative (not adjunct)** to conventional chest physical therapy. Because published clinical data have not suggested that these devices are associated with an increased health benefit, their use would primarily represent a convenience to the individual. It is on this basis that they are considered not medically necessary (unless conventional chest physical therapy has failed or is unavailable).

Evidence Review

Description

Oscillatory devices are alternatives to the standard daily percussion and postural drainage method of airway clearance for individuals 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.

Background

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extra-thoracic. Some devices require the active participation of individuals. They include oscillating positive expiratory pressure devices, such as Flutter and Acapella, in which the individual 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 counter-weighted 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 individual. Positive expiratory pressure therapy requires individuals 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 (e.g., 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 individuals 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 individuals with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and COPD. Additionally, they could benefit individuals with neuromuscular disease who have impaired cough clearance.

This policy addresses the outpatient use of oscillatory devices. This policy does not address inpatient device use (e.g., in the immediate postsurgical period).

Oscillation and lung expansion devices (e.g., Volara System, MetaNeb 4 System, and BiWase Clear System) purportedly provide three therapies in a single device: continuous positive expiratory pressure (CPEP), continuous high flow oscillations (CHFO), and nebulizer provided aerosolized medications in a home care setting. These devices are intended for the mobilization of secretions, lung expansion, prevention and treatment of atelectasis, and for the delivery of medication and oxygen during CPEP and CHFO.

Summary of Evidence

For individuals who have cystic fibrosis who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. The relevant outcomes are

symptoms, quality of life (QOL), 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. The relevant outcomes are symptoms, QOL, hospitalizations, and medication use. A 2015 systematic review identified seven small RCTs on several types of oscillatory devices; only one reported the clinically important outcomes of exacerbations or hospitalizations. Only three RCTs reported on QOL, 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 chronic obstructive pulmonary disease (COPD) who receive oscillatory devices, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, QOL, 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 (e.g., lack of intention to treat analysis and between-group comparisons). Moreover, the published studies reported mixed findings and did not consistently 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 two RCTs and a systematic review. The relevant outcomes are symptoms, QOL, hospitalizations, and medication use. One of the RCTs was not powered to detect statistically significant differences. The other RCT, conducted in individuals with amyotrophic lateral sclerosis (ALS), 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 that the technology results in an improvement in the net health outcome.

For individuals using oscillation and lung expansion devices, there is insufficient published credible scientific evidence which permits conclusions regarding the net health outcome of these devices.

Additional Information

Clinical input obtained in 2008 supported the use of oscillatory devices to treat individuals with cystic fibrosis and bronchiectasis, in certain situations. The most commonly mentioned clinical criteria were individuals who failed or were intolerant of other methods of mucus clearance and individuals 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 individual.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03299231	Oscillating Positive Expiratory Pressure Device for Mucous Clearing in Severe Exacerbation of COPD Requiring Hospitalization Targeting Outcome: A Randomized, Double Blind, Sham Controlled Trial (SIMPLE)	160	Oct 2024
NCT07037303	Comparison of Effectiveness Between Active Cycle of Breathing Techniques (ACBT) and Oscillating Positive Expiratory Pressure (OPEP, Aerobika) Device Assisted Treatment in Patients With Bronchiectasis in Korea: A Randomized Controlled Trial	100	Jul 2028
Unpublished			
NCT04271969	Clinical Effectiveness of High Frequency Chest Wall Oscillation (HFCWO) in a Bronchiectasis Population	125	Dec 2023
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 No.	Trial Name	Planned Enrollment	Completion Date
NCT04582214[a]	A Pilot Study of the Use of Oscillation and Lung Expansion (OLE) Therapy in Patients Hospitalized With COVID-19	6	June 2022 (status unknown)
NCT05366010[a]	Evaluation of Oscillation and Lung Expansion (OLE) Using The Volara System for Treatment of Respiratory Complications in Patients With Neuromuscular Disease in the Home Setting	70	June 2023 (terminated)

NCT: national clinical trial.

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 two 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 individuals who failed or were intolerant of other methods of mucus clearance and individuals who lacked caregivers to provide chest physical therapy. Input did not support use of oscillatory devices for the treatment of chronic obstructive pulmonary disease (COPD).

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.[20]

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).[21]

Cystic Fibrosis Foundation

In 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence.[22] 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).

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several oscillatory devices have been cleared for marketing by the US Food and Drug Administration through the 510(k) process, including those listed in **Table 2**.

Table 2. Select Oscillatory Devices Cleared by the U. S. Food and Drug Administration

Device	Manufacturer	Clearance Date
Flutter Mucus Clearance Device	Axcan Scandipharm (for marketing in the United States)	1994
Vestä 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
The Vest APX System	Baxter Healthcare Corporation	2024
LibAirty Airway Clearance System	Synchrony Medical Ltd	2024
AllPEP	Enchant Tek Co. Ltd	2024

PEP: positive expiratory pressure. US Food and Drug Administration product codes: BYI, BYT, BWF.

In 2022, the FDA granted 510(k) clearance (K213564) for the marketing of BiWaze Clear System as it was considered substantially equivalent to a predicate device (Volara System and MetaNeb4 System). It is indicated for the "mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with an oxygen supply. It's intended use is for adults and children over the age of 5 years in the home care setting. It is noted to provide 3 therapies: Positive Expiratory Pressure (PEP), Oscillation, and Nebulize. It can be used with a facemask, mouthpiece, or a trach adapter.

In 2020, the FDA granted 510(k) clearance (K200988) for the marketing of the Volara Oscillation and Lung Expansion device (formerly known as Maximus System) as it was considered

substantially equivalent to the predicate device, MetaNeb 4 System. It is indicated for the "mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and it can provide supplemental oxygen when used with oxygen supply. This modification from an earlier predicate device (K192143) was to add the ability to provide aerosol from a nebulizer via a Ventilator Tee adapter during Continuous High Frequency Oscillations (CHFO) mode when connected to a ventilator. It is intended for use in adults and children over 5 years old in the home care setting.

Note: On July 16, 2024, the FDA published a class 1 recall for certain lots of the Volara system single-patient use circuit and blue ventilator adapter assembly. This is due to reports of the handset plug disconnecting from the nebulizer port on the blue ventilator adapter. Baxter Healthcare notified customers to immediately cease all use of the affected lot numbers.

Note: On June 23, 2022, the FDA published a Class I recall for the Volara system with in-line ventilator adapter (OPTIMUS Handset 2) or Volara patient circuit kit (OPTIMUS OLE AC Patient Circuit Kit). Baxter Healthcare Corporation and its subsidiary company Hill-Rom recalled the Volara system because the in-line ventilator adaptor may prevent home-use individuals from getting enough oxygen from their ventilators.

In 2016, the FDA granted 510(k) clearance (K151689) for the marketing of the MetaNeb 4 System as it was considered substantially equivalent to predicate devices, MetaNeb (K124032) and IPV Bird (K895485). It is indicated for "mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and it can provide supplemental oxygen when used with compressed oxygen. It is intended for use in adults and children over 5 in the home care setting. The system has three modes: aerosol-for delivery of aerosol only. In this mode CHFO and CPEP are not available. CHFO (Continuous High Frequency Oscillation) and CPEP (Continuous Positive Expiratory Pressure).

FDA Product Code: NHJ.

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History

Date	Comments
05/10/11	Add to Durable Medical Equipment Section - New medical policy. This policy replaced 1.01.115.
04/25/12	Replace policy. Policy updated with literature review. References 12, 13 and 14 added. No changes to policy statements.
08/24/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
04/16/13	Replace Policy. Rationale section for COPD updated based on literature review through January 2013. References 13, 14 added; others renumbered or removed. Policy statement unchanged.
04/14/14	Annual Review. In the first 2 medically necessary statements, brand named Flutter or Flutter and Acapella devices changed to generic “oscillatory positive expiratory pressure device”. In the second policy statement, "standard chest physiotherapy treatment" changed to "standard treatment". Policy updated with literature review through December 20, 2013. References 2, 7, 8, 9 and 13 added; others renumbered/removed. Policy statements wording changed as noted, intent unchanged. Coding update; ICD-9 procedure code 93.18 and ICD-10 PCS codes; HCPCS code S8185 removed – this is a low dollar item.
04/24/15	Annual Review. Policy updated with literature review through December 15, 2014. Reference 1 added. Policy statements unchanged. Remove ICD-9 and ICD-10 codes removed; these are not utilized in policy adjudication.

Date	Comments
12/23/15	Policy Statement update, minor formatting error fixed.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review through April 25, 2016; references 5, 12, and 14-16 added. Patients with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, “disorders” changed to “conditions”.
04/11/17	Policy moved into new format. Reformatted the Evidence Review section. No change to policy statements.
08/01/17	Annual Review, approved July 18, 2017. Policy updated with literature review through April 25, 2017; reference 9 added. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered not medically necessary when criteria are not met (previously considered investigational).
09/01/18	Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; no references were added. Policy statements unchanged.
09/01/19	Annual Review, approved August 6, 2019. Policy updated with literature review through April 2019; reference removed. Policy statement unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021; approved October 13, 2020. No changes to policy statements.
12/01/20	Interim Review, approved November 19, 2020. Policy updated with literature review through August 13, 2020; no references were added. Policy statements unchanged.
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through April 19, 2021; references added. Policy statements unchanged.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through April 18, 2022; references added. Minor editorial refinements made to policy statements; intent unchanged.
10/01/22	Coding update. Updated description of HCPCS code E0483.
07/01/23	Policy renumbered, approved June 13, 2023, from 1.01.15 to 1.01.539 Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions. Policy reformatted for greater ease of understanding. Some text moved to new additional guidelines section. Added policy statement that oscillation and lung expansion devices are considered investigational. References added. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through April 19, 2023; reference added. Policy statements unchanged.

Date	Comments
10/01/24	Coding update. Added new HCPCS codes A7021 and E0469 effective 10/1/2024. Added unlisted HCPCS code, E1399.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through April 22, 2024; no references added. Policy statements unchanged.
11/01/25	Annual Review, approved October 13, 2025. Policy updated with literature review through July 1, 2025; reference added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.