01.01.01 Airway Clearance Devices in the Home Setting

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Related Policies

None

Summary

Description

Note: This medical policy only applies to airway clearance devices in the home setting.

Airway clearance devices are alternatives to the standard daily percussion and postural drainage method of airway clearance for individuals with hypersecretory lung disease (i.e., produce excessive mucus) or neurodegenerative/neuromuscular disease with documented, associated respiratory muscle weakness or diaphragm paralysis. There are several types of devices including but not limited to high-frequency chest compression with an inflatable vest, oscillating positive expiratory pressure devices, and mechanical insufflation-exsufflation 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 and other miscellaneous 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. However, even though there is a paucity in the peer-reviewed scientific evidence in showing consistent evidence regarding the effectiveness of oscillatory devices for cystic fibrosis individuals, for certain carefully-selected individuals this treatment is widely considered to be in accordance with generally accepted standards of medical practice in the United States and is supported by relevant profession societies (see Practice Guidelines and Position Statements) and will be considered medically necessary when the criteria below are met, see Policy.

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. However, even though there is a paucity in the peer-reviewed scientific evidence in showing consistent evidence regarding the effectiveness of oscillatory devices for bronchiectasis individuals, for certain carefully-selected individuals this treatment is widely considered to be in accordance with generally accepted standards of medical practice in the United States and is supported by relevant profession societies (see Practice Guidelines and Position Statements) and will be considered medically necessary when the criteria below are met, see Policy.

For individuals who have chronic obstructive pulmonary disease (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 (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. However, even though there is a paucity in the peer-reviewed scientific evidence in showing consistent evidence regarding the effectiveness of oscillatory (vibratory) positive expiratory pressure oscillatory devices for individuals with COPD, for certain carefully selected individuals this treatment is considered medically necessary when the criteria below are met, see Policy.

For individuals who have respiratory conditions related to neuromuscular disorders who receive oscillatory devices or mechanical insufflator-exsufflator (MI-E) devices, the evidence includes 2 RCTs and 4 systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication ruse. 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 regarding the primary outcomes in

pulmonary function measures, or in most secondary outcomes. Although the systematic reviews for MI-Es show an immediate beneficial effect, additional RCTs or SRs are needed showing longer-term lung function improvement. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. However, even though there is a paucity in the peer-reviewed scientific evidence in showing consistent evidence regarding the effectiveness of high-frequency oscillatory chest wall compression or MIEs for individuals who have respiratory conditions related to neuromuscular disorders, for certain carefully-selected individuals this treatment is considered medically necessary when the criteria below are met, see Policy.

For individuals with respiratory disorders or respiratory conditions related to neuromuscular disorders who utilize additional miscellaneous airway devices including but not limited to the combination high frequency chest oscillation and positive expiratory pressure systems (e.g., MetaNeb) oroscillation lung expansion (OLE) (e.g. Volara, BiWaze Clear) Wellmark did not identify any systematic reviews or RCTs. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. Since there were no identified studies that directly evaluated whether using the additional miscellaneous airway devices improves the health outcomes such as change in symptoms, quality of life, hospitalizations, and medication use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

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.

OBJECTIVE

The objective of this evidence review is to determine whether in home airway clearance devices improve the net health outcomes in individuals with respiratory diagnoses and other disorders.

PRIOR APPROVAL

Not applicable.

POLICY

Note: This medical policy only applies to airway clearance devices in the home setting.

High-Frequency Chest Wall Compression/ High-Frequency Chest Wall Oscillator (E0483)/Vibralung® (E1399): *(i.e., Smartvest and inCourage)*

Medically Necessary

A high-frequency oscillatory chest wall compression device for airway clearance may be **medically necessary** in lieu of chest physiotherapy, where there is documentation of failure of standard treatments and recurrent disease exacerbations (see Policy Guidelines) in individuals with **one** of the following:

- Chronic diffuse bronchiectasis and **one of the following**:
    - With a daily productive cough for at least six continuous months; **or**

    - With exacerbations requiring antibiotic therapy more than two times a year;

  And the following:
    - Confirmed by high resolution or spiral chest computed tomography scan; **or**
- Cystic fibrosis; **or**
- A neurodegenerative/neuromuscular disease with documented, associated respiratory muscle weakness or diaphragm paralysis

A **Vibralung® Acoustical Percussor (E1399)** may be **medically necessary** when **all** of the following criteria are met:

- The above criteria for a high frequency chest wall compression device is met; **and**
- The individual is unable to use another high frequency chest wall compression device (i.e., burns, chest trauma, rib fractures).

Oscillatory (Vibratory) Positive Expiratory Pressure Device (E0484/S8185) (*i.e., Flutter®, Acapella®, AirobikA®, RCCornet®*):

Medically Necessary

An oscillatory (vibratory) positive expiratory pressure device for airway clearance may be considered **medically necessary** in individuals who have difficulty clearing secretions and *recurrent disease exacerbations (see Policy Guidelines) who have been diagnosed with **one of the following**:

- Bronchiectasis
- Chronic obstructive pulmonary disease (COPD) with excessive secretion production including chronic bronchitis
- Cystic fibrosis

Mechanical Insufflation-Exsufflation Devices (E0482):

Medically Necessary

A mechanical insufflation-exsufflation device for airway clearance may be considered **medically necessary** for an individual with **all of the following**:

- a neuromuscular disease (e.g., muscular dystrophy, multiple sclerosis, amyotrophic lateral sclerosis, high-spinal cord injury); **and**
- a significant chest wall impairment and/or diaphragmatic movement; **and**
- documentation of failure of standard treatments (see Policy Guidelines).

Investigational

An airway clearance device that does not meet the above criteria is considered **investigational** including but not limited to the following because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

- Combination high frequency chest oscillation and positive expiratory pressure systems (e.g., MetaNeb)

Oscillation lung expansion devices (e.g. Volara, BiWaze Clear)

Replacement for Airway Clearance Devices (A7025, A7026):

Medically Necessary

The replacement of an existing airway clearance device is considered **medically necessary** when **one of the following** criteria are met:

- The individual meets the medical necessity criteria above for the specific airway clearance device and documentation confirms the airway clearance device is malfunctioning, no longer under warranty and cannot be repaired; or
- The individual meets the medical necessity criteria above for the specific airway clearance device and documentation from a health care provider recommending the replacement is needed due to growth or change of the individual's condition.

Not Medically Necessary

The replacement of an existing airway clearance device is considered **not medically necessary** including but not limited to the following:

- When the above medical necessity replacement criteria are not met.
- The replacement is solely for better technology or improved aesthetics.

POLICY GUIDELINES

Standard Treatment Documentation Requirements:

Documentation includes **one or more** of the following:

- The caregiver is physically or mentally incapable of performing chest physiotherapy (CPT) as prescribed; **or**
- No caregiver, parent, or partner resource available to perform standard chest physiotherapy (CPT) as prescribed; **or**
- Standard chest physiotherapy (CPT) is not tolerated; **or**
- Failure* of standard chest physiotherapy (CPT) to adequately mobilize retained secretions (e.g., prior history of pneumonia or worsening of pulmonary condition), when CPT has been performed as prescribed.

And all of the following:

- Have difficulty clearing secretions: **and**
- Have recurrent disease exacerbations (e.g., acute onset warranting additional treatment to the individual's underlying condition more than two times a year).

Definitions

- **Bronchiectasis**: A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or from a congenital condition.

- **Bronchitis**: An inflammation of the upper airways associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last two or more years, a person has been coughing up some mucus every day for at least three months out of the year.

- **Chest physiotherapy (CPT)** (also known as chest physical therapy): The use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is

to improve mucociliary clearance and pulmonary function to reduce the risk of infection and lung damage.

- **Cystic fibrosis (CF)**: An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF.

- ***Failure of Standard of Treatments**: Failure includes repeat respiratory infections or decreased breathing capacity when there is evidence that chest physiotherapy (CPT) has been consistently performed as prescribed.

- ***Recurrent Disease Exacerbations**: acute onset warranting additional treatment to the individual's underlying condition more than two times a year.

Coding

See the Codes table for details.

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 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 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

A mechanical insufflation-exsufflation device is an example of a cough stimulation apparatus. It helps facilitate secretion clearance by applying positive pressure to the airway and then rapidly shifts to negative pressure. The quick pressure changes trigger a high expiratory flow rate mimicking a cough. A report by the American College of Chest Physicians stated that "[t]he inability of patients with respiratory muscle weakness to achieve high lung volumes is likely to contribute to cough ineffectiveness. Increasing the inhaled volume prior to cough by air-stacking positive pressure breaths or by glossopharyngeal breathing increases cough expiratory flows by 80 % in these patients. Cough efficiency may be further

enhanced by the application of negative pressure to the airway for a period of 1 to 3 seconds. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold."

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 individuals t 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 individuals with neuromuscular disease who have impaired cough clearance.

This evidence review addresses the outpatient use and does not address inpatient device use (e.g., in the immediate postsurgical period).

Regulatory Status

Several airway clearance devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, including but not limited to the following:

Table 1: High Frequency Oscillatory Chest Compression Devices (HFCWO)

Device	FDA 510(k) Approval Year	Description
AffloVest® (International Biophysics)	2013	It is designed to provide patients the freedom and mobility by a portable device which runs via battery pack, hose, and generator. Patients can customize and enhance airway clearance therapy, help mobilize lung secretions, and promote treatment adherence for patients with Bronchiectasis, Cystic Fibrosis, COPD, MS, MD (muscular dystrophy), ALS, and other neuromuscular and respiratory diseases.
inCourage® System	2005	The InCourage system, a high-frequency chest wall oscillation (HFCWO) device features active venting, which is designed to enable deep breaths during therapy, enhance comfort and help encourage adherence for people with chronic respiratory conditions, like bronchiectasis, COPD, cystic fibrosis and various neuromuscular and neuromotor conditions.

Device	FDA 510(k) Approval Year	Description
MetaNeb® System (Hill-Rom)	2016	It delivers continuous high-frequency oscillation and positive expiratory pressure to facilitate pulmonary mucus clearance and provide lung expansion. The system is indicated for mobilizing lung secretions, lung expansion therapy, and treating and preventing pulmonary atelectasis. The device can be used in patients with chronic obstructive pulmonary disease, postoperative airway management, bronchiectasis, neuromuscular disorders, cystic fibrosis, asthma, emphysema, and chest wall trauma.
MedPulse® Respiratory Vest System (*different models available)	2004	It produces oscillating pressurized air-pulses that are delivered to the Inflatable Vest by the Vest/Generator Hose. The air-pulses produced by the Generator cause the Vest to rapidly inflate and deflate against the external chest wall of a patient to promote airway clearance by creating HFCWO resulting in mobilization of bronchial secretions.
Monarch™ Airway Clearance System (Hill-Rom)	2017	It is a portable version of a high frequency chest wall oscillation device utilizing pulmonary oscillating discs (PODs) containing magnets, over the upper and lower lobes of the lungs.
Respin11 Bronchial Clearance System (Respinnovation)	2012	Developed for an effective therapy of airway obstruction conditions. The device is made up of a jacket connected to a vibration/pulsation generator. the pulsations are obtained by the pressure differences of a multistage blower. These pulsations are transmitted to the subject's chest through an air pressure piston system specially designed and inserted into the front and rear cavities of the vest provided. The compression then release cycle on the chest wall generates a differential air speed in the bronchial airway in the lungs. This produces a shearing effect which pulls the mucus off the bronchial airway walls and to then be moved through mucociliary action into the larger upper airways to then be eliminated naturally through coughing or if necessary, by external suction.
SmartVest® (Electromed)	2013	Is designed to promote airway clearance and improve bronchial drainage when external chest manipulation is the physician's treatment of choice. The Air Pulse Generator produces small volumes of pressurized air pulses that are rapidly delivered to the Inflatable Vest via

Device	FDA 510(k) Approval Year	Description
		the Air Hose at a selected oscillatory frequency between 5-20 times per minute (Hz). The Inflatable Vest imparts the oscillatory air pulses as pressure forces to the patient's external chest wall. These pressurized air pulses promote transient increases in airflow within the lungs that loosens mucus sufficiently to facilitate expulsion by the patient when normal respiratory function is not capable.
The Vest™ Airway Clearance System (Hill-Rom)	2003	It 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. This was originally approved in 1988 under ABI vest.
The Vest™ APX System (Baxter)	2024	This system uses the same airflow technology as The Vest System, Model 105 from Hill-Rom. It provides high-frequency chest compression using an inflatable vest and an air-pulse generator using a large-bore tubing. It generates pressure pulses that cause the vest to inflate and deflate against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions. Changes have been made to enhance the design and ease of use. Changes include a slimmed down vest, touchscreen, lighter design, improved comfort and new color options.
LibAirty™ Clearance System (Synchrony Medical Ltd.)	2024	This system combines sequential chest compressions with autogenic drainage airway clearance device. Regulated compressions are delivered by an inflatable vest made of several air chambers that applies oscillating pressure to the chest and back. A control device with a display screen, operation buttons and air compressor that is used with a mobile application. The user can adjust treatment and receive coaching on breathing with the application.

Table 2: Mechanical Insufflation – Exsufflation Device

Device	FDA 510(k) Approval Year	Description
Philips CoughAssist	2020	It is designed to non-invasively inflate the lung with positive pressure and assist cough by shifting the air to negative pressure to help mobilize secretions out of the airway. A report by the American College of Chest Physicians stated that "[t]he inability of patients with respiratory muscle weakness to achieve high lung volumes is likely to contribute to cough ineffectiveness. Increasing the inhaled volume prior to cough by air-stacking positive pressure breaths or by glossopharyngeal breathing increases cough expiratory flows by 80 % in these patients. Cough efficiency may be further enhanced by the application of negative pressure to the airway for a period of 1 to 3 seconds. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold." “On September 12, 2023, Philips Respironics discontinued the Philips CoughAssist T70. Philips Respironics stated they will continue to support service and provide repair parts and accessories as long as parts and accessories are available, but, in any event, no longer than through the end of service October 1, 2028.”
Synclara™ Cough Assist Device System	N/A	The Synclara™ Cough Assist Device System is described by manufacturer as "The Synclara Cough System is designed to help pediatric and adult patients who need medical assistance to cough effectively due to diaphragm weakness, respiratory weakness or a weak or ineffective cough caused by respiratory conditions or neuromuscular disorders."

Table 3: Miscellaneous Device(s)

Device	FDA 510(k) Approval Year	Description
Pulsehaler™	2021	The Pulsehaler™ is indicated for use as a positive expiratory pressure (PEP) Device delivering vibrating air pressure pulses into the airway to assist in secretion clearance and airway opening. Air pulses are created by the interruption of the flow of air to and from the patient by a spinning disc.

Device	FDA 510(k) Approval Year	Description
Simeox Airway Clearance Technology (Physio Assist)	At this time, the device is not FDA approved for use in the United States.	Simeox technology is reported to mobilize and transport mucus from the distal tracts by disseminating a vibratory pneumatic signal in the bronchial tree during exhalation.
Vibralung® Acoustical Percussor (Westmed)	2014	It is an acoustical percussor device that is battery-operated and portable. It applies vibratory sound waves directly to your airways through your mouth, at a multitude of frequencies. Reported to be a gentler form of ACT than oscillatory PEP devices.
Volara™ System (Hill-Rom)	2020	This device is an oscillating and lung expansion (OLE) device, designed as a single device to provide therapies, continuous expiratory pressure (CPEP), continuous high flow oscillations (CHFO), and aerosolized medication.
BiWAZE® Cough	2020	The FDA describes the BiWaze as follows: "The BiWaze Cough is a device intended for clearing bronchopulmonary secretions. The therapy provided by BiWaze Cough mimics a cough and consists of three phases which mimic a cough; inhale, exhale, and pause phase. The inhale phase is positive airway pressure to expand the lungs. Then the exhale phase is a sudden shift to negative pressure to pull the air out of lungs. Finally, the pause phase provides positive pressure which keeps the airways open in between the therapy cycle."
Lung Flute® (Medical Acoustics LLC)	2006	Is an acoustic positive expiratory pressure therapy device. It is a tubular device that has a plastic mouthpiece and Mylar reed that flutters during use. The sound waves that are made mobilize and clear secretions.

Table 4: Vibratory/Oscillatory Positive Expiratory Pressure (PEP) Devices

Device	FDA 510(k) Approval Year	Description
Acapella® (DHD Healthcare)	1999	It 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.
AerobiKA® oscillating PEP device (Trudell Medical)	2013	It is oscillating PEP (oPEP) device. It is a single patient use, handheld secretion clearance and lung expansion device that creates vibrating positive expiratory pressure when a patient exhales through the device. The device may be used simultaneously with aerosol drug delivery from a nebulizer.
FLUTTER® (Axcan Scandipharm)	1994	It is similar in concept as the Acapella but uses a counterweighted plug and magnet to create air flow oscillation.
AllPEP (Enchant Tek Co. Ltd.)	2024	It is an oscillating PEP (oPEP) device. The device is similar to the Acapella device, however the AllPEP utilizes a swinging flap valve which generates oscillation during exhalation.
RC-Cornet ® Mucus Clearing Device (PARI Respiratory Equipment)	1999	It is an oscillating PEP (oPEP) device that consists of a semi-cirular plastic tube. Air is exhaled into the device through a curved plastic tube that contains a flexible, latex-free hose. Exhalation causes the tube to strike the top and bottom of the plastic tube, which occludes flow and causes oscillations and positive expiratory pressure in the patient's airway. Accessories can be added to allow for use of non ISO nebulizers.
iPEP® system including PocketPEP® and vPEP® (D R Burton Healthcare)	2016	It is an oscillating PEP (oPEP) device that combines incentive spirometer therapy. This device is similar to the Acapella except for using a flap valve along with the combined incentive spirometer.

RATIONALE

This evidence review was created in February 1995 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Cystic Fibrosis

Clinical Context and Therapy Purpose

The purpose of an airway clearance device use in individuals who have cystic fibrosis (CF) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with CF.

Interventions

The therapy being considered is the application an airway clearance device (i.e. an oscillatory PEP and Vibralung). Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators

The following therapy is currently being used: standard chest physical therapy.

Outcomes

The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions caused by a mucous buildup in the lungs, QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A number of RCTs and a Cochrane systematic review of RCTs have evaluated oscillatory devices for treating patients with CF. The Cochrane review addressed a variety of oscillatory devices, was last updated by Morrison and Milroy (2020) and is summarized in the table below. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and QOL measures. Meta-analysis was limited due to the variety of devices, outcome measures, and lengths of follow-up used. Reviewers concluded that there was a lack of evidence supporting the superiority of oscillatory devices versus any other form of physical therapy, that one device was superior over another, and that there is a need for adequately powered RCTs with long-term follow-up.

Table 5: Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Morrison et al 2020	Inception to July 2019	39	Patients with cystic fibrosis	1114 (4-166)	RCT and controlled studies	2 d to 2.8 y

Randomized Controlled Trials

Representative recent RCTs follow. Trial characteristics and results as well as gaps related to relevance, study design, and conduct are summarized in the tables below.

McIlwaine et al (2013) published an RCT comparing high-frequency chest wall oscillation (HFCWO) with PEP mask therapy. The primary outcome measure was the number of pulmonary exacerbations requiring an antibiotic. At the end of 1 year, patients in the PEP arm had a statistically significant lower incidence of pulmonary exacerbations requiring antibiotics compared with HFCWO group. The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group (p=.02). There were no statistically significant differences in pulmonary measures, including the forced expiratory volume in 1 second (FEV_1).

Sontag et al (2010) published a multicenter RCT that compared postural drainage, the Flutter device, and HFCWO. At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat analysis found no significant differences between treatment groups in the modeled rate of decline for percent predicted FEV_1 or forced vital capacity (FVC). The small sample size and high dropout rate limited the conclusions drawn from this trial.

Pryor et al (2010) evaluated 75 patients 16 years of age and older with CF from a single center in the U.K. Sixty-five (87%) of 75 patients completed the trial and were included in the analysis. Although the study was described as a noninferiority trial, it was not statistically analyzed as such. Instead, no statistically significant differences among the regimens in the primary outcome measure of FEV_1 were

construed as evidence for noninferiority.

The following study is not represented in the study tables within this review.

Radtke et al (2018) evaluated 15 adult patients with CF using the Flutter device with moderate-intensity interval cycling exercise to measure pulmonary diffusing capacity. The outcomes of interest included pulmonary function, sputum viscosity and volume, hospitalization rate, and QOL measures. The results yielded no differences in absolute changes in pulmonary diffusion capacity. This study is not represented in the study tables within this review.

Table 6: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
McIlwaine et al (2013)	Canada	12	2008 - 2012	Children with CF age >6 y (N=107)	HFCWO (n=56)	PEP mask therapy (n=51)
Sontag et al (2010)	U.S.	20	1999-2002	Adults and children with CF (N=166)	2 active Tx: flutter (n=58) and vest (n=57)	Postural drainage (n=58)
Pryor et al (2010)	U.K.	1	NR	Patients with CF ≥16 y (N =75)	Cornet (n=15), Flutter (n=15), PEP (n=15), autogenic drainage (n=15)	Active cycle of breathing technique (n=15)

CF: cystic fibrosis; HFCWO: high-frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; Tx: treatment.

Table 7: Summary of Key Randomized Controlled Trial Results

Study	N	No. of PEs Requiring Antibiotics	Spirometry	Quality of Life
McIlwaine et al (2013)	107		Cannot confirm	Not applicable
HFCWO			Data not reported	Outcome not evaluated
n		96		
Median		2.00		
Range		1.00-3.00		
Positive expiratory pressure			Data not reported	Outcome not evaluated
n		49		
Median		1.00		
Range		0.00-2.00		
p		.007	No difference	Not applicable

Study	N	No. of PEs Requiring Antibiotics	Spirometry	Quality of Life
Sontag et al (2010)				
Flutter		Outcome not evaluated	Data not reported	Outcome not evaluated
Vest		Outcome not evaluated	Data not reported	Outcome not evaluated
Postural drainage		Outcome not evaluated	Data not reported	Outcome not evaluated
p			No difference	
Pryor et al (2010)	65	Not applicable		Not applicable
Active cycle of breathing techniques		Outcome not evaluated	FEV_1 at 0 mo: 2.01; FEV_1 at 12 mo: 1.94	Small improvement (0.7)[a]
Autogenic drainage		Outcome not evaluated	FEV_1 at 0 mo: 2.68; FEV_1 at 12 mo: 2.64	Small improvement (0.5)[a]
Cornet		Outcome not evaluated	FEV_1 at 0 mo: 1.93; FEV_1 at 12 mo: 1.90	No difference (<0.5)[a]
Flutter		Outcome not evaluated	FEV_1 at 0 mo: 2.46; FEV_1 at 12 mo: 2.43	Moderate improvement (1.3)[a]
Positive expiratory pressure		Outcome not evaluated	FEV_1 at 0 mo: 2.17; FEV_1 at 12 mo: 2.02	Small improvement (0.8)[a]
p		Not applicable	No difference	Not reported

FEV_1: forced expiratory volume in 1 second; HFCWO: high-frequency chest wall oscillation; PE: pulmonary exacerbations.
[a] Minimal important differences in the Chronic Respiratory Questionnaire. A change of 0.5 represents a small difference in symptoms, 1.0 a moderate difference, and 1.5 a large difference

Table 8: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
McIlwaine et al (2013)					
Sontag et al (2010)					
Pryor et al (2010)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms

Table 9: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
McIlwaine et al. (2013)	3. Allocation concealment unclear	1.Not blinded to treatment assignment		1. Eighty-eight (82%) of 107 randomized patients completed the trial. Trial limitations were a nearly 20% dropout rate.	4. Trial stopped early without enrolling expected number of patients and might have been underpowered to detect clinically significant differences between groups	
Sontag et al. (2010)	3. Allocation concealment unclear	1.Not blinded to treatment assignment		1. Dropout rates were high; trial ended early: 35 (60%), 16 (31%), and 5 (9%) patients withdrew from the postural drainage, Flutter, and Vest groups, respectively. Most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13) and lack of time (n=7).	4. Trial ended earlier than planned	
Pryor et al. (2010)	3. Allocation concealment unclear	1. Not blinded to treatment		1. Ten of 75 randomized patients were lost to follow-up		

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		assignment				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Miscellaneous Devices

Vibralung

Randomized Controlled Trial

Wheatley et al (2018) evaluated the safety of the Vibralung and collected preliminary data on its ability to mediate sputum expectoration in individuals with cystic fibrosis in an RCT. “Two separate studies, 10 and 11 mild to moderate CF patients were recruited for study I and II, respectively. Study I: Vibralung was used for 20 min with either no sound (NS: PEP only) or sound (S: PEP and sound) on randomized visits. Pulmonary function, diffusion capacity of the lungs for carbon monoxide and nitric oxide (DL_{CO}/DL_{NO}), symptoms, and peripheral oxygen saturation (SpO_2) were measured at baseline and at 1 and 4 h post treatment. Expectorated sputum was collected over 4 h post treatment. Study II: over 5 days of in-hospital therapy, the Vibralung or vibratory vest therapy (Vest) were used for two therapy sessions per day, with sputum collected for 20 min following each therapy and pulmonary function accessed pre and post each 5-day period (days 1–5 or 7–11) in a randomized crossover design. Vibralung usage resulted in no change from baseline to 4 h post in pulmonary function, SpO_2 or symptoms ($p > 0.05$). At 4 h post therapy, the DL_{CO}- and DL_{NO}-derived measure of alveolar–capillary unit function (DM/V_C) showed improvement (DM/V_C = 12.5 ± 5.5 *versus* 7.3 ± 18.8% change, S *versus* NS) with no difference between S and NS ($p = 0.74$). Sputum expectoration was similar between S and NS conditions (wet sputum = 10.5 ± 4.6 *versus* 9.9 ± 3.2 g, S *versus* NS, $p = 0.25$). There were no differences in the improvement in pulmonary function between Vibralung and Vest during either 5-day period during the hospital stay. Vibralung was well tolerated and caused no detrimental changes in pulmonary function metrics. The Vibralung appears to be a safe ACT in individuals with CF.

Section Summary: Cystic Fibrosis

A number of RCTs evaluating oscillatory devices have reported mixed findings and had limitations (e.g., small sample sizes, large dropout rates). A systematic review identified 39 RCTs comparing oscillatory devices with other recognized airway clearance techniques; some were published only as abstracts. The study findings were not pooled due to heterogeneity in designs and outcome measures. The systematic review concluded that results from additional RCTs with adequate power and long-term follow-up would permit conclusions on the effect of oscillatory devices on outcomes for CF.

Bronchiectasis

Clinical Context and Therapy Purpose
The purpose airway clearance devices (i.e. an oscillatory PEP) in individuals who have bronchiectasis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with bronchiectasis.

Interventions
The therapy being considered is the application of airway clearance devices (i.e. an oscillatory PEP). Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators
The following therapy is currently being used: standard chest physical therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (e.g., pulmonary exacerbations), QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Lee et al (2015) published a Cochrane review of airway clearance techniques for treating bronchiectasis, which is summarized in the Table 10 below. Of 7 RCTs included, 6 were crossover trials. Five trials used a PEP device, 1 used HFCWO, and 1 used postural drainage. Reviewers did not pool study findings due to heterogeneity among studies. Primary outcomes of interest were pulmonary exacerbations, hospitalizations for bronchiectasis, and QOL.

Table 10: Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Lee et al. (2015)	1966-2015	7 RCTs	Adults and children diagnosed with bronchiectasis based on plain-film chest radiography,	1107 (8-37)	1 RCT, 6 crossover RCTs	Immediate (within 24 h) and "long-term" (>24 h)

Study	Dates	Trials	Participants	N (Range)	Design	Duration
			bronchography, high-resolution computed tomography, or physician diagnosis			

RCT: randomized controlled trial.

Randomized Controlled Trials

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 11 and 12. Gaps related to relevance, study design, and conduct are summarized in Tables 13 and 14.

Murray et al (2009) reported on a crossover study with 20 patients. The number of exacerbations did not differ statistically at 12 weeks. Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Cochrane reviewers noted that the study was not blinded, and that patient reported QOL measures may have been subject to bias.

Herrero-Cortina et al (2016) reported on a crossover RCT with 31 patients. The interventions were temporary PEP, autogenic drainage, and slow expiration with the glottis opened in the lateral position. There were no significant differences among treatments in the mean sputum clearance during the 24-hour period after each intervention, cough severity (measured using the total Leicester Cough Questionnaire [LCQ] score), or lung function measures (e.g., FEV_1).

Livnat et al (2021) conducted a randomized trial in 51 patients with bronchiectasis that compared autogenic drainage and oscillating PEP for daily airway clearance. Patients who had not previously performed airway clearance were included. After 4 weeks, the primary outcome (lung clearance index, calculated as the cumulative expired volume during the washout phase divided by the functional residual capacity) and FEV1 did not differ between groups. Change in sputum quantity from randomization to study end did not differ between groups. The rate of exacerbations was not described, but some quality-of-life measures improved throughout the study in both groups.

Table 11: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Murray et al. (2009)	U.K.	1	NR	Patients radiologically diagnosed with bronchiectasis (N=20)	Acapella Choice (n=20)	No chest physical therapy (n=20)
Herrero-Cortina et al. (2016)	Spain	1	2010-2013	Patients radiologically diagnosed with bronchiectasis (N=31)	Slow expiration with glottis opened in lateral posture (n=31) and temporary PEP (n=31)	Autogenic drainage (n=31)

Study	Countries	Sites	Dates	Participants	Interventions	
Livnat et al. (2021)	Israel	1	2017-2019	Patients radiologically diagnosed with bronchiectasis (N=51)	Aerobika (n=24)	Autogenic drainage (n=25)

NR: not reported; PEP: positive expiratory pressure l.

Table 12: Summary of Key Randomized Controlled Trial Results

Study	Total LCQ Score Difference	24-h Sputum Volume Difference, mL	No. of Exacerbations
	Median (IQR)	Median (IQR)	
Murray et al (2009)	N=20	N=20	Not applicable
Acapella	1.3 (-0.17 to 3.25)	2 (0 to 6)	5
No Acapella	0 (-1.5 to 0.5)	-1 (-5 to 0)	7
p	.002	.02	.48
Herrero-Cortina et al (2016)			
Autogenic drainage	0.5 (0.1 to 0.5);.01	-1.4 (5.1 to 1.2)	Not studied
ELTGOL	0.9 (0.5 to 2.1);.001	-1.6 (-4.8 to 1.0)	Not studied
TPEP	0.4 (0.1 to 1.2);.04	-2.5 (-8.6 to 0.1)	Not studied
p	See above	.01	Not applicable
Livnat et al. (2021)			
Aerobika	Not studied	-10	Not studied
Autogenic drainage	Not studied	-2.2	Not studied
p	Not applicable	.386	Not applicable

ELTGOL: expiration with glottis opened in lateral posture; IQR: interquartile range; LCQ: Leicester Cough Questionnaire; TPEP: temporary positive expiratory pressure.

Table 13: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Murray et al (2009)					
Herrero-Cortina et al (2016)					1, 2. 24-h follow-up is not enough
Livnat et al (2021)				1. No data on exacerbations	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 14: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Murray et al (2009)	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician			3. Power not based on clinically important difference	
Herrero-Cortina et al (2016)		1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician			1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference	
Livnat et al (2021)		1. Not blinded to treatment assignment (participants)				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment,
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d]Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Bronchiectasis

A 2015 systematic review identified 7 small RCTs assessing several types of oscillatory devices; only 1 reported the clinically important outcomes of exacerbations or hospitalizations. Three reported on QOL, and trial findings were mixed. A 2016 crossover RCT did not find a significant benefit of temporary PEP compared with other airway clearance techniques.

Chronic Obstructive Pulmonary Disease (COPD)

Clinical Context and Therapy Purpose

The purpose of airway clearance devices (i.e. oscillatory PEP therapy) in individuals who have chronic obstructive pulmonary disease (COPD) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with COPD.

Interventions

The therapy being considered is the application of an airway clearance device. Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators

The following therapy is currently being used: standard therapy.

Outcomes

The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (e.g., pulmonary exacerbations), QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Systematic reviews have evaluated studies of airway clearance techniques in patients with COPD. Two early reviews addressed various techniques (i.e., they were not limited to studies on oscillatory devices) while the most recent review was specific to oscillatory devices. These are summarized in the table below. Studies included in the systematic reviews were mostly small and reviewers noted that the quality of evidence was generally poor. The meta-analysis conducted by Alghamdi et al. found oscillatory PEP reduced exacerbations (odds ratio, 0.37; 95% confidence interval [CI], 0.19 to 0.72) and improved 6-minute walk distance (mean difference, 49.8 m; 95% CI, 14.2 to 85.5 m), but the authors also noted the need for higher-quality studies.

Table 15: Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ides et al (2011)	1980-2008	26	Patients with COPD	659 (7-58)	Not reported	Unclear
Osadnik et al (2012)	Inception to 2009 (PEDro) or 2011 (CAGR)	28	Participants with investigator-defined COPD, emphysema or chronic bronchitis	907 (5-96)	RCTs (parallel and crossover)	24 h to >8 wk
Alghamdi et al (2020)	Inception to March 2020	8	Patients with COPD	381 (15-120)	RCTs and crossover	5 d to 2 y

CAGR: Cochrane Airways Group Specialised Register of trials; COPD: chronic obstructive pulmonary disease; PEDro: Physiotherapy Evidence Database; RCT: randomized controlled trial.

Randomized Controlled Trials

Representative recent RCTs follow. Trial characteristics and results as well as gaps related to relevance, study design and conduct are summarized in Tables 16-19.

Chakrovorty et al (2011) reported on the results of a crossover RCT among patients with moderate-to-severe COPD and mucus hypersecretion. Patients received HFCWO or conventional treatment in random order, for 4 weeks, with a 2-week washout period between treatments. The primary outcome was QOL as measured using the St. George's Respiratory Questionnaire (SGRQ). Only 1 of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared with baseline, with a decrease in mean score from 72 to 64 (p=.02). None of the 4 SGRQ dimensions improved after conventional treatment. There were no significant pre- to posttreatment differences in secondary outcomes (e.g., FEV_1, FVC).

Svenningsen et al (2016) reported on results of an unblinded, industry-funded, randomized crossover study. Each intervention period lasted 21 to 28 days. In the nonsputum producers, scores differed significantly only on the Patient Evaluation Questionnaire total score. In patients who were sputum-producers at baseline, pre- versus post-PEP scores differed significantly for FVC, 6-minute walk distance, SGRQ total score, and the Patient Evaluation Questionnaire ease of bringing up sputum and patient global assessment subscales. It is unclear if the interventions were clinically meaningful. The crossover studies had similar limitations including no between-group comparisons (i.e., outcomes after oscillatory device use vs. the control intervention), lack of intention-to-treat analysis, and short-term follow-up (immediate posttreatment period).

Goktalay et al (2013) reported on the results of a parallel-group RCT. Patients were randomized to 5 days of treatment with medical therapy plus HFCWO (n=25) or medical therapy only (n=25). At day 5, outcomes including FEV_1, modified Medical Research Council dyspnea scale scores, and the 6-minute walk distance, did not differ significantly between groups. This short-term trial included hospitalized patients who might differ from COPD patients treated on an outpatient basis.

Alghamdi et al (2023) compared the Acapella device to usual care in patients with stable COPD (N=122). The primary outcome was the change from baseline in LCQ score. Results demonstrated significant improvement in LCQ scores with the use of Acapella compared to usual care.

Table 16: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Chakrovorty et al (2011)	U.K.	1	NR	Patients with at least 1 COPD exacerbation with FEV_1 <0.8, FEV_1/FVC <0.7, and a daily wet sputum volume of >25 mL (N=38) (female, n=8; male, n=30)	SmartVest Airway Clearance System (n=22)	No SmartVest Airway Clearance System (n=22)
Svenningsen et al (2016)	Canada	1	NR	COPD patients self-identified as sputum-producers or non-sputum-producers (N=32) (female, n=13; male, n=14)	Oscillatory PEP (AerobiKA device) (n=27)	No oscillatory PEP (n=27)
Goktalay et al (2013)	Turkey	1	2009-2011	Patients with stage 3 or 4 COPD hospitalized for COPD exacerbations (N=50) (female, n=1; male, n=49)	HFCWO plus medical Tx (n=25)	Medical Tx only (n=25)
Alghamdi et al (2023)	NR	1	2020-2021	Stable COPD patients self-identified as sputum producers every day or most days (N=122) (female, n=49; male n=73)	Oscillatory PEP (Acapella) (n=61)	Usual care, including active cycle of breathing technique (n=61)

COPD: chronic obstructive pulmonary disease; FEV_1: forced expiratory volume in 1 second; FVC: forced vital capacity; HFCWO: high-frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; Tx: treatment.

Table 17: Summary of Key Randomized Controlled Trial Results

Study	SGRO Total Scores	BODE Index	LCQ Score Change from Baseline
Chakrovorty et al (2011)			
SmartVest	Baseline: 63; End of treatment: 60	Not assessed	
No SmartVest	Baseline: 62; End of treatment:62	Not assessed	
p	NS	Not applicable	
Svenningsen et al (2016)			
Oscillatory positive expiratory pressure	Sputum-producers: 40 (12); Non-sputum-producers: 36	Not assessed	
Control	Sputum-producers: 49; Non-sputum-producers:35	Not assessed	
p	.01 (sputum-producers);.64 (non-sputum-producers)	Not applicable	
Goktalay et al (2013)			
HFCWO plus medical treatment	Not assessed	Day 0: 7.72; Day 3: 7.00; Day 5: 6.44	
Medical treatment only	Not assessed	Day 0: 7.72; Day 3: 7.48; Day 5: 7.24	
p	Not applicable	Uninterpretable	
Alghamdi et al (2023)			
Oscillatory positive expiratory pressure			1.54 (0.33 to 2.18)
Usual care			0.51 (0.34 to 1.89)
MD (95% CI); p			

BODE: body mass index, airflow obstruction, dyspnea, and exercise; HFCWO: high-frequency chest wall oscillation; NS: not significant; SGRO: St George's Respiratory Questionnaire.

Table 18: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Chakrovorty et al (2011)					
Svenningsen et al (2016)					

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Goktalay et al (2013)					1. Not sufficient duration for benefits (short-term follow-up for 5 d)
Alghamdi et al (2023)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Tale 19: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Chakrovorty et al (2011)	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up or missing data: 8 out of 30 withdrew due to COPD exacerbations	2. Power not calculated for primary outcome	
Svenningsen et al (2016)	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. High loss to follow-up or missing data: 16% withdrew from trial	2. Power not calculated for primary outcome	
Goktalay et al (2013)	1. Participants not randomly allocated 2. Allocation not concealed	1. Not blinded to treatment assignment 2. Not blinded outcome			1. Power calculations not reported 2. Power not calculated for	

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		assessment 3. Outcome assessed by treating physician			primary outcome 3. Power not based on clinically important difference	
Alghamdi et al (2023)		1. Not blinded to treatment assignment		1. High loss to follow-up or missing data: 15% lost to follow-up and 9% with no follow-up data for objective monitoring		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
COPD: chronic obstructive pulmonary disease.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Chronic Obstructive Pulmonary Disease

Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tended to use intention-to-treat analysis and between-group comparisons. The published studies reported mixed findings and did not support the use of oscillatory devices in individuals with COPD.

Respiratory Conditions Related to Neuromuscular Disorders

Clinical Context and Therapy Purpose

The purpose of airway clearance devices or in individuals who have respiratory conditions related to neuromuscular disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with respiratory conditions related to neuromuscular disorders.

Interventions
The therapy being considered is the application of airway clearance devices. Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators
The following therapy is currently being used: standard therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (e.g., pulmonary exacerbations), QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

High-Frequency Chest Wall Oscillation (HFCWO)

Systematic Reviews
A Cochrane review by Winfield et al (2014) evaluated the nonpharmacologic management of respiratory morbidity in children with severe global developmental delay treated with airway clearance techniques. Reviewers included RCTs and nonrandomized comparative studies. They identified 3 studies on HFCWO (1 RCT, 2 pre-post) and one on PEP (pre-post), with sample sizes from 15 and 28 patients. As a result of heterogeneity, a meta-analysis was not conducted. The review is summarized in the Table 20.

Table 20: Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Winfield et al (2014)	Inception to Nov 2013	15	Children up to 18 y with a diagnosis of severe neurologic impairment and respiratory morbidity	Not reported	RCTs and nonrandomized comparative studies	Unclear

RCT: randomized controlled trial.

Randomized Controlled Trials
Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 21 and 22. Gaps related to relevance, study design and conduct are summarized in Tables 23 and 24.

Yuan et al (2010) stated that airway secretions and infections are common in cerebral palsy (CP) and neuromuscular diseases. Chest physiotherapy is standard therapy, but effort is substantial. High-frequency chest wall oscillation (HFCWO) is used in CF, but tolerability and safety data in cerebral palsy and neuromuscular disease are limited. These researchers performed a prospective, randomized, controlled trial of HFCWO and standard CPT in patients with neuromuscular disease or CP. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, chest radiographs, and polysomnography. Caregivers were questioned regarding therapy adherence. A total of 28 participants enrolled, 23 completed (12 CPT, mean study period 5 months). No adverse outcomes were reported. Adherence to prescribed regimen was higher with HFCWO ($p = 0.036$). These findings suggest safety, tolerability, and better compliance with HFCWO. Improvement in airway clearance may help prevent hospitalizations. The authors noted that larger controlled trials are needed to confirm these results.

Lange et al (2006) did an exploratory randomized controlled trial, assessed changes in respiratory function in patients with amyotrophic lateral sclerosis (ALS) after using HFCWO. This was a 12-week study of HFCWO in patients with probable or definite ALS, an Amyotrophic Lateral Sclerosis Functional Rating Scale respiratory subscale score less than or equal to 11 and greater than or equal to 5 and forced vital capacity (FVC) greater than or equal to 40 % predicted. A total of 46 patients were enrolled (58.0 +/- 9.8 years; 21 men, 25 women); 22 used HFCWO and 24 were untreated. Only 35 completed the trial: 19 used HFCWO and 16 untreated. Results were reported per-protocol, rather than by intention-to-treat. HFCWO users had less breathlessness ($p = 0.021$) and coughed more at night ($p = 0.048$) at 12 weeks compared to baseline. At 12 weeks, HFCWO users reported a decline in breathlessness ($p = 0.048$); non-users reported more noise when breathing ($p = 0.027$). There were no significant differences in FVC change, peak expiratory flow, capnography, oxygen saturation, fatigue, functional quality of life, or transitional dyspnea index. When patients with FVC between 40 and 70 % predicted were analyzed, FVC showed a significant mean decrease in untreated patients but not in HFCWO patients; HFCWO patients had significantly less increased fatigue and breathlessness. Satisfaction with HFCWO was 79 %. The authors concluded that HFCWO was well-tolerated, considered helpful by a majority of patients, and decreased symptoms of breathlessness. In patients with impaired breathing, HFCWO decreased fatigue and showed a trend toward slowing the decline of forced vital capacity. The investigators explained that the study was exploratory in nature and was not sufficiently powered to detect significant differences in clinical outcomes such as pulmonary complications, hospitalizations, or mortality.

Table 21: Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Yuan et al (2010)	U.S.	1	NR	Patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic (N=28) (Hispanic, n=9; White, n=7; Asian, n=4; African American, n=2; Pacific Islander, n=1)	HCFWO (n=12)	Standard chest physical therapy (n=11)

Study	Countries	Sites	Dates	Participants	Interventions	
Lange et al (2006)	U.S.	6	NR	Adults with amyotrophic lateral sclerosis (N=46)	HCFWO (n=22)	No treatment (n=24)

HFCWO: high-frequency chest wall oscillation; NR: not reported.

Table 22: Summary of Key Randomized Controlled Trial Results

Study	Hospitalization/IV Antibiotics	TDI (proportion showing worsening)
Yuan et al (2010)	N=23	
HCFWO	0/12	Not assessed
Standard chest physical therapy	4/11	Not assessed
p	.09	Not applicable
Lange et al (2006)	-	N=18
HCFWO	Not assessed	Functional impairment: 27.8%; Magnitude of task: 38.9%; Magnitude of effort: 27.8%
No treatment	Not assessed	Functional impairment: 43.8%; Magnitude of task: 50%; Magnitude of effort: 56.2%
p	Not applicable	Functional impairment:.331; Magnitude of task:.515; Magnitude of effort:.092

HFCWO: high- frequency chest wall oscillation; IV: intravenous; TDI:Transitional Dyspnea Index.

Table 23: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Yuan et al (2010)					
Lange et al (2006)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 24: Study Design and Conduct Limitations

Study	Allocation [a]	Blinding [b]	Selective Reporting [c]	Data Completeness [d]	Power [e]	Statistical [f]
Yuan et al (2010)	1. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment (except chest X-rays) 3. Outcome assessed by treating physician		1. High loss to follow-up or missing data 12% missing data and all in treatment group	1, 2, 3. Trial was exploratory and was not powered to detect statistically significant findings of the primary outcomes	
Lange et al (2006)	1. Allocation not concealed	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up or missing data 15% missing data at 12 wk	2. Power not calculated for primary outcome 3. Power not based on clinically important difference	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Mechanical Insufflator-Exsufflator (MI-E)

Systematic Reviews

Veldhoen et al (2023) conduced a systematic review and meta-analysis of the effects of daily use of MI-E in those with a neuromuscular disease. The outcomes that were studies included severity and prevalence of respiratory infections and characteristics, lung function, and patient satisfaction. A total of 608 participants involving 25 studies were included. Three studies were RCTs (Kim, 2016; Lacombe, 2014; Rafiq, 2015). The overall beneficial effect was seen on analysis when comparing MI-E on cough peak

flow (CPF) to unassisted CPF (mean difference 91.6 L/min [95% confidence interval {CI}, 28.3–155.0], p<0.001). Majority of studies reported high satisfaction with MI-E although this result could be influenced by selection and study bias. The authors concluded that there is limited data analyzing MI-E effect of on hospital admissions or respiratory tract infections. Although MI-E had an immediate beneficial effect on CPF, additional RCTs or SRs showing longer-term lung function improvement are needed.

Morrow et al (2021) conducted a Cochrane review of cough augmentation techniques for people with chronic neuromuscular disorders that included 11 RCTs and quasi-RCTs (N=287). Analyses indicated improvements in peak cough flow compared to unassisted cough. However, authors rated the evidence certainty as 'very low' due to important limitations, including small sample sizes, wide confidence intervals, and short-term follow-up.

In April of 2015 Hayes completed a Health Technology Assessment (HTA) which was last reviewed in April of 2017 on the CoughAssist MI-E (Respironic/Philips) for respiratory insufficiency. Hayes gave CoughAssist MI-E (Respironic/Philips) for respiratory insufficiency a C rating. According to Hayes a C rating indicates, "potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains regarding safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns."

Section Summary: Respiratory Conditions Related to Neuromuscular Disorders

Two RCTs and a systematic review have evaluated oscillatory devices for the treatment of respiratory conditions in neuromuscular disorders. One RCT was not powered to detect statistical significance. The other, conducted in amyotrophic lateral sclerosis patients, did not find statistically significant improvement after HCFWO compared with usual care for the primary outcomes (pulmonary function measures) or most secondary outcomes. Additionally, a pilot study on ALS which was not adequately powered did not find HFCO to be of significant help. Three systematic reviews have evaluated MI-E devices for the treatment of respiratory conditions in neuromuscular disorders. Evidence may suggest a benefit in the identified health outcomes, however additional, higher-quality RCTs with long-term follow up are needed.

Combination High Frequency Chest Oscillation and Positive Expiratory Pressure Systems (e.g., Metaneb)

Clinical Context and Therapy Purpose

The purpose of combination high frequency chest oscillation and positive expiratory pressure system therapy in individuals who have respiratory conditions or respiratory conditions related to neuromuscular disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with have respiratory conditions or respiratory conditions related to neuromuscular disorders.

Interventions

The therapy being considered is the application of airway clearance devices. Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators
The following therapy is currently being used: standard therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (e.g., pulmonary exacerbations), QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Section Summary: Combination High Frequency Chest Oscillation and Positive Expiratory Pressure Systems (e.g., Metaneb)
No studies were identified that were adequately powered that have directly evaluated whether using the combination high frequency chest oscillation and positive expiratory pressure systems (e.g., Metaneb) for respiratory disorders or respiratory conditions related to neurodegenerative disorders / neuromuscular disorders improves the health outcomes such as quality of life, change in disease status or morbid events.

Oscillation Lung Expansion (OLE)

Clinical Context and Therapy Purpose

The purpose of Oscillation Lung Expansion (OLE) therapy in individuals who have respiratory conditions or respiratory conditions related to neuromuscular disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with have respiratory conditions or respiratory conditions related to neuromuscular disorders.

Interventions
The therapy being considered is Oscillation Lung Expansion (OLE)

. Airway clearance devices are intended to be used primarily in the home setting by individuals themselves.

Comparators
The following therapy is currently being used: standard therapy.

Outcomes

The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (e.g., pulmonary exacerbations), QOL, hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

We only identified one study by Kontudious et al. 2024 that only evaluated aerosol delivery efficiency outcomes. We did not identify any studies that evaluated our clinical outcomes of interest.

Section Summary: Oscillation Lung Expansion (OLE)

No studies were identified that were adequately powered that have directly evaluated whether using the Volara and BiWaze Clear systems for respiratory disorders or respiratory conditions related to neurodegenerative disorders/ neuromuscular disorders improves the health outcomes such as quality of life, change in disease status or morbid events.

SUPPLEMENTAL INFORMATION

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

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 (ACCP)

In 2006 the ACCP indicated that devices designed to oscillate gas in the airway (e.g., Flutter, Intrapulmonary Percussive Ventilation, HFCWC), either directly or by compressing the chest wall, may be considered an alternative to chest PT in patients with CF (level of evidence, low; benefit, conflicting; grade of recommendation, inconclusive.

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 committee determined that, although there is a paucity of controlled trials that assess the long-term effects of ACTs, the evidence quality overall for their use in CF is fair and the benefit is moderate. The committee recommends airway clearance be performed on a regular basis in all patients. There are no ACTs demonstrated to be superior to others, so the prescription of ACTs should be individualized. (Level of evidence: fair; net benefit: moderate; grade of recommendation: B).

National Institute for Health and Clinical Excellence (NICE)

In 2017, NICE published the Cystic Fibrosis: Diagnosis and Management Guideline which was last updated in 2022. In the guidance on the management of cystic fibrosis, do not offer high-frequency chest wall oscillation as an airway clearance technique for people with cystic fibrosis except in exceptional clinical circumstances. The specialist cystic fibrosis team will decide whether these circumstances apply, and their decision would then be subject to the NHS England policy on Individual Funding Requests. Be aware that the evidence shows high-frequency chest wall oscillation is not as effective as other airway clearance techniques.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	No code(s)	
HCPCs		
	A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
	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
	E0482	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each
	E0483	Oscillatory positive expiratory pressure device, non-electric, any type, each

	E0484	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each
	E1399	Durable medical equipment, miscellaneous
	S8185	Flutter device
Type of Service	Pulmonary	
Place of Service	Home	

POLICY HISTORY

Date	Reason	Action
September 2025	Annual Review	Policy Renewed
September 2024	Annual Review	Policy Revised
August 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Revised
September 2018	Annual Review	Policy Revised
September 2017	Annual Review	Policy Revised
May 2017	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
June 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Revised

Date	Reason	Action
October 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Revised
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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