1.01.15	Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions		
Original Policy Date:	December 1, 2004	**Effective Date:**	August 1, 2023
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 24

Policy Statement

I. Use of an oscillatory positive expiratory pressure (PEP) device (e.g., Flutter® or Acapella® device) may be considered **medically necessary** in individuals with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.

II. High-frequency chest wall (HFCW) compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** in individuals with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography [CT] scan) when **either** of the following occurs:
   A. Standard chest physical therapy has failed
   B. Standard chest physical therapy is unavailable or not tolerated

III. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, are considered **investigational,** including, but not limited to, their use for **any** of the following:
   A. In individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above
   B. As an adjunct to chest physical therapy
   C. In other lung diseases such as chronic obstructive pulmonary disease (COPD)
   D. Respiratory conditions associated with neuromuscular disorders

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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

For this policy, chronic diffuse bronchiectasis is defined by a daily productive cough for at least 6 continuous months or exacerbations more than 2 times per year requiring antibiotic therapy and confirmed by high-resolution or spiral chest computed tomography scan.

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

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process including the following:

- Oscillatory Positive Expiratory Pressure (Active Devices):
  - Acapella® Vibratory PEP Therapy System (DHD Healthcare, Wampsville, NY) in 1999
  - AerobiKA (Trudell Medical, London, ON) in 2013
  - Flutter® Mucus Clearance Device (Axcan Scandipharm Inc., Birmingham, AL) in 1994
  - RC Cornet™ Mucus Clearing Device (PARI Respiratory Equipment, Inc., Midlothian, VA) in 1999
- High-Frequency Chest Wall Compression (Passive Devices):
  - inCourage® System (Respiratory Technologies, Lakeville, MN) in 2005
  - The Vest™ Airway Clearance System (Hill-Rom Services, Inc., St. Paul, MN) - formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by the FDA—most recently a fifth generation device.
- Intrapulmonary Percussive Ventilation
  - Bird IPV® Noncontinuous Ventilator (Percussionaire Corp., Sagle ID) in 1989
  - PowerNeb™ Noncontinuous Ventilator (Comedica Incorporated, Dallas, TX) in 2005
  - Vibralung Acoustical Percussor (Westmed Inc., Tucson AZ) in May 2014

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 do not suggest that these devices are associated with an increased health benefit, their use primarily represents a convenience to the patient, and it is on this basis that they are considered not medically necessary (unless conventional chest physical therapy has failed or is unavailable).

Description

Oscillatory devices are alternatives to the standard daily percussion and postural drainage method of airway clearance for patients with cystic fibrosis. There are several types of devices including high-frequency chest compression with an inflatable vest and oscillating positive expiratory pressure devices, such as the Flutter and Acapella devices. Respiratory therapists and other providers may also use oscillatory devices for other respiratory conditions such as diffuse bronchiectasis, chronic obstructive pulmonary disease (COPD), and respiratory conditions associated with neuromuscular disorders.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

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

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

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

Rationale

Background

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require the active participation of patients. They include oscillating positive expiratory pressure devices, such as Flutter and Acapella, in which the patient exhales multiple times through a device. The Flutter device is a small pipe-shaped, easily portable handheld device, with a mouthpiece at one end. It contains a high-density, stainless steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, the vibration of the airways occurs, resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create air flow oscillation.

Other airway clearance techniques also require active patient participation. For example, autogenic drainage and an active cycle breathing technique both involve a combination of breathing exercises performed by the patient. Positive expiratory pressure therapy requires patients to exhale through a resistor to produce positive expiratory pressures during a prolonged period of exhalation. It is hypothesized that the positive pressure supports the small airway such that the expiratory airflow can better mobilize secretions.

High-frequency chest wall oscillation devices (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 patients with cystic fibrosis, also known as chest physical therapy. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, often a parent if the

patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles. Oscillatory devices can also potentially be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

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

Literature Review

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Cystic Fibrosis

Clinical Context and Therapy Purpose

The purpose of oscillatory positive expiratory pressure (PEP) therapy 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 of oscillatory PEP. Oscillatory PEP devices are intended to be used primarily in the home setting by patients 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),[1] and is summarized in Table 2. 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 2. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Morrison et al 2020[1]	Inception to July 2019	39	Patients with cystic fibrosis	1114 (4-166)	RCTs and controlled studies	2 d to 2.8 y

RCT: randomized controlled trial.

Randomized Controlled Trials
Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 3 and 4. Gaps related to relevance, study design, and conduct are summarized in Tables 5 and 6.
McIlwaine et al (2013) published an RCT comparing high-frequency chest wall oscillation (HFCWO) with PEP mask therapy.[2] 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.[3] 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.[4] 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.[5,] 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.

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
McIlwaine et al (2013)[2,]	Canada	12	2008 -2012	Children with CF age >6 y (N=107)	HFCWO (n=56)	PEP mask therapy (n=51)
Sontag et al (2010)[3,]	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)[4,]	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 4. Summary of Key Randomized Controlled Trial Results

Study	N	No. of PEs Requiring Antibiotics	Spirometry	Quality of Life
McIlwaine et al (2013)[2,]	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
Sontag et al (2010)[3,]				
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)[4,]	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 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
McIlwaine et al (2013)[2,]					
Sontag et al (2010)[3,]					
Pryor et al (2010)[4,]					

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 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
McIlwaine et al (2013)[2,]	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,]	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)[4,]	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. Ten of 75 randomized patients were lost to follow-up		

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: 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 of oscillatory PEP therapy 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 an oscillatory PEP. Oscillatory PEP devices are intended to be used primarily in the home setting by patients 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 Table 7.[6] 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 7. Characteristics of Systematic Reviews

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

RCT: randomized controlled trial.

Randomized Controlled Trials

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 8 and 9. Gaps related to relevance, study design, and conduct are summarized in Tables 10 and 11.

Murray et al (2009) reported on a crossover study with 20 patients. The number of exacerbations did not differ statistically at 12 weeks.[7] 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.[8] 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.[9] 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 FEV_1 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 QOL measures improved throughout the study in both groups.

Table 8. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Murray et al (2009)[7]	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)[8]	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)
Livnat et al (2021)[9]	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.

Table 9. 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)[7],	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)[8],			
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)[9],			
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 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Murray et al (2009)[7],					
Herrero-Cortina et al (2016)[8],					1, 2. 24-h follow-up is not enough
Livnat et al (2021)[9],				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 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Murray et al (2009)[7],	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by			3. Power not based on clinically important difference	

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		treating physician				
Herrero-Cortina et al (2016)[8,]		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)[9,]		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

Clinical Context and Therapy Purpose

The purpose of 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 oscillatory PEP. Oscillatory PEP devices are intended to be used primarily in the home setting by patients 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.[10,11,12,] Two early reviews addressed various techniques (ie, they were not limited to studies on oscillatory devices) while the most recent review was specific to oscillatory devices. These are summarized in Table 12. 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.[13,]

Table 12. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ides et al (2011)[10,]	1980-2008	26	Patients with COPD	659 (7-58)	Not reported	Unclear
Osadnik et al (2012)[11,]	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)[13,]	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 are summarized in Tables 13 and 14. Gaps related to relevance, study design and conduct are summarized in Tables 15 and 16.

Chakrovorty et al (2011) reported results of a crossover RCT among patients with moderate-to-severe COPD and mucus hypersecretion.[14,] 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 the results of an unblinded, industry-funded, randomized crossover study.[15,] 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 (ie, 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.[16,] 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).[13,] 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 13. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Chakrovorty et al (2011)[14,]	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)[15,]	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)[16,]	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)[13,]	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 14. Summary of Key Randomized Controlled Trial Results

Study	SGRO Total Scores	BODE Index	LCQ score change from baseline
Chakrovorty et al (2011)[14,]			
SmartVest	Baseline: 63; End of treatment: 60	Not assessed	
No SmartVest	Baseline: 62; End of treatment:62	Not assessed	
p	NS	Not applicable	

Study	SGRO Total Scores	BODE Index	LCQ score change from baseline
Svenningsen et al (2016)[15,]			
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)[16,]			
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)[13,]			
Oscillatory positive expiratory pressure			1.54 (0.33 to 2.18)
Usual care			0.51 (0.34 to 1.89)
MD (95% CI); p			1.03 (0.71 to 2.10);.03

BODE: body mass index, airflow obstruction, dyspnea, and exercise; CI: confidence interval; HFCWO: high-frequency chest wall oscillation; LCQ: Leicester Cough Questionnaire; MD: mean difference; NS: not significant; SGRO: St George's Respiratory Questionnaire.

Table 15. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Chakrovorty et al (2011)[14,]					
Svenningsen et al (2016)[15,]					
Goktalay et al (2013)[16,]					1. Not sufficient duration for benefits (short-term follow-up for 5 d)
Alghamdi et al (2023)[13,]					

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 16. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Chakrovorty et al (2011)[14,]	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. High loss to follow-up or missing data: 8	2. Power not calculated for	

Study	Allocation[a]	Blinding[b]	Selective Reporting [c]	Data Completeness [d]	Power [e]	Statistical[f]
		2. Not blinded outcome assessment 3. Outcome assessed by treating physician		out of 30 withdrew due to COPD exacerbations	primary outcome	
Svenningsen et al (2016)[15],	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)[16],	1. Participants not randomly allocated 2. Allocation not concealed	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	
Alghamdi et al (2023)[13],		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 patients with COPD.

Respiratory Conditions Related to Neuromuscular Disorders

Clinical Context and Therapy Purpose

The purpose of oscillatory PEP therapy 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 an oscillatory PEP. Oscillatory PEP devices are intended to be used primarily in the home setting by patients 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
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.[17,] 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 Table 17.

Table 17. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Winfield et al (2014)[17,]	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 18 and 19. Gaps related to relevance, study design and conduct are summarized in Tables 20 and 21.
Yuan et al (2010) reported results of a parallel-arm RCT.[18,] Both groups were instructed to perform the assigned treatment for 12 minutes, 3 times a day for the study period (mean, 5 months). There were no statistically significant differences between groups on primary outcomes. No therapy-related adverse events were reported in either group.

Lange et al (2006) reported on the results of a parallel-arm RCT in adults with amyotrophic lateral sclerosis.[19,] Patients were randomized to 12 weeks of HCFWO or usual care. There were no statistically significant between-group differences in pulmonary measures (FVC predicted, capnography, oxygen saturation, or peak expiratory flow). There was also no significant difference in the amyotrophic lateral sclerosis Functional Rating Scale respiratory subscale score (worsening) at 12 weeks. Of symptoms assessed as secondary outcomes, there was significantly less breathlessness and night cough in the HCFWO group than in the usual care group, and groups did not differ significantly on other symptoms, including the noise of breathing, suction frequency, suction amount, day cough, and nocturnal symptoms.

Table 18. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Yuan et al (2010)[18,]	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)
Lange et al (2006)[19,]	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 19. Summary of Key Randomized Controlled Trial Results

Study	Hospitalization/IV Antibiotics	TDI (proportion showing worsening)
Yuan et al (2010)[18,]	N=23	
HCFWO	0/12	Not assessed
Standard chest physical therapy	4/11	Not assessed
p	.09	Not applicable
Lange et al (2006)[19,]	-	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 20. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Yuan et al (2010)[18,]					
Lange et al (2006)[19,]					

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 21. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting [c]	Data Completeness [d]	Power [e]	Statistical[f]
Yuan et al 2010)[18,	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)[19,	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.

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.

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

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).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 22.

Table 22. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04271969	Clinical Effectiveness Of High Frequency Chest Wall Oscillation (HFCWO) In A Bronchiectasis Population	100	Jul 2023
NCT05548036	A Feasibility Randomised Control Trial (RCT) of Aerobika TM Verses Active Cycle of Breathing Technique (ACBT) in People With Chronic Obstructive Pulmonary Disease (COPD) (TIPTOP)	120	Apr 2024
Completed			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05034900	Does Addition of Oscillatory Positive Expiratory Pressure (OPEP) Device to a Chest Physiotherapy Program Provide Further Health Benefits in Children With Bronchiectasis?	42	Sept 2022

NCT: national clinical trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
- Diagnosis being treated with the request and why the device is needed
- Previous treatment plan(s) and response(s)
- Clinical findings and duration of daily productive cough and or frequency of exacerbations of chronic diffuse bronchiectasis if applicable
- Documentation of reasons why standard chest physical therapy cannot be performed, is unavailable, or is not tolerated
- Documentation of frequent exacerbations of respiratory distress
- CT scan results to confirm chronic diffuse bronchiectasis if applicable

Post Service (in addition to the above, please include the following):

- Results/reports of outcomes with device utilization

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	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
	E0480	Percussor, electric or pneumatic, home model

Type	Code	Description
	E0481	Intrapulmonary percussive ventilation system and related accessories
	E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each
	E0484	Oscillatory positive expiratory pressure device, nonelectric, any type, each
	S8185	Flutter device

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2004	Administrative Review Administrative review of external experts by Policy Committee, accepted as New Policy
06/01/2005	Administrative Review with statement unchanged
12/07/2006	Policy Revision Indication updated - BCBSA MPP
09/12/2008	Policy Review and revision. Policy title change. Prior Policy title: Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders.
07/01/2011	Policy revision with position change
09/27/2013	Policy revision with position change
06/30/2015	Coding Update Policy revision without position change
08/01/2016	Policy title change from Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders Policy revision without position change
08/01/2017	Policy revision with position change
08/01/2018	Policy revision without position change
02/01/2019	Coding update
08/01/2019	Policy revision without position change
08/01/2020	Annual review. No change to policy statement.
12/01/2020	Policy guidelines and literature updated.
08/01/2021	Annual review. No change to policy statement. Literature review updated.
08/01/2022	Annual review. Policy statement, guidelines and literature updated.
08/01/2023	Annual review. No change to policy statement. Literature review updated

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with

generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions 1.01.15 **Policy Statement:** I. Use of an oscillatory positive expiratory pressure (PEP) device (e.g., Flutter® or Acapella® device) may be considered **medically necessary** in individuals with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations. II. High-frequency chest wall (HFCW) compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** in individuals with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography [CT] scan) when either of the following occurs: A. Standard chest physical therapy has failed B. Standard chest physical therapy is unavailable or not tolerated III. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, are considered **investigational**, including, but not limited to, their use for any of the following: A. In individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above B. As an adjunct to chest physical therapy C. In other lung diseases such as chronic obstructive pulmonary disease (COPD) D. Respiratory conditions associated with neuromuscular disorders	**Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions 1.01.15** **Policy Statement:** I. Use of an oscillatory positive expiratory pressure (PEP) device (e.g., Flutter® or Acapella® device) may be considered **medically necessary** in individuals with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations. II. High-frequency chest wall (HFCW) compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** in individuals with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography [CT] scan) when either of the following occurs: A. Standard chest physical therapy has failed B. Standard chest physical therapy is unavailable or not tolerated III. Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, are considered **investigational**, including, but not limited to, their use for any of the following: A. In individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above B. As an adjunct to chest physical therapy C. In other lung diseases such as chronic obstructive pulmonary disease (COPD) D. Respiratory conditions associated with neuromuscular disorders