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Airway Clearance Devices

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Oscillatory Positive Expiratory Pressure Devices
Use of an oscillatory positive expiratory pressure 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.

High-Frequency Chest Wall Compression Devices and Intrapulmonary Percussive Ventilation Devices

High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices **may be considered medically necessary** in individuals with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (**see Policy Guidelines section**) (including chest computed tomography scan) when there is a demonstrated need for airway clearance and either:

- 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 (e.g., unavailability, intolerance).

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices **are considered experimental, investigational and/or unproven**, including, but not limited to, their use:

- In individuals with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above;
- As an adjunct to chest physical therapy; and
- In other lung diseases such as chronic obstructive pulmonary disease or respiratory conditions associated with neuromuscular disorders.

NOTE 1: This policy addresses outpatient use of oscillatory devices. This policy does not address inpatient device use (e.g., in the immediate postsurgical period).

MECHANICAL IN-EXSUFFLATION DEVICES

Mechanical in-exsufflation devices **may be considered medically necessary** in individuals with neuromuscular disease whose condition is causing a significant impairment of chest wall and/or diaphragmatic movement, such that it results in an inability to clear retained secretions.

Policy Guidelines

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

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

Description

Normal clearance of airways rests on three basic components: a patent airway, mucociliary clearance, and an adequate cough. Patients with a variety of neuromuscular and respiratory diseases may have impaired cough responses, abnormal airway clearance, or increased sputum production, which may lead to respiratory failure due to the inability to clear profuse respiratory secretions.

Oscillatory Devices

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.

Mechanical Insufflation-Exsufflation Devices

Individuals with neuromuscular disease or spinal cord injury may have a weakened capacity to cough that limits their ability to expel mucus from the lungs, which increases the risk of choking and incidence of recurrent respiratory tract infections. Mechanical insufflation-exsufflation is designed to deliver alternative cycles of positive and negative pressure. The positive pressure causes air to enter the lungs, followed by a rapid drop in pressure that causes exsufflation. One such device, the CofFlator was first marketed during the 1950s but fell into disuse with the popularity of tracheostomy and suctioning as a technique of ventilatory support. Subsequently, the concept for the device was reactivated and the device redesigned, resulting in 1993 U.S. Food and Drug Administration (FDA) approval of the In-Exsufflator. (JH Emerson Co, Cambridge, MA). The device, which may also be referred to as a "coughalator," is designed to deliver insufflation-to-exsufflation pressure of about +40 to –40 cm H20, which in turn simulates a powerful cough by creating an expiratory flow of 10L/sec. Cycling between insufflation and exsufflation can either be performed manually or automatically. Five or more treatments are generally given in 1 session until no further secretions are expelled, and hemoglobin desaturations related to mucous plugging are resolved.

Regulatory Status

Several oscillatory devices have been cleared for marketing by the U.S. FDA 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	Hill-Rom	2015

System		
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.

FDA product codes: BYI, BYT.

A number of mechanical insufflation-exsufflation devices have been cleared by the FDA for mobilization of endobronchial secretions, including the Synclara™ Cough System (Hill-Rom Holdings, Inc., Chicago, IL), BiWaze® Cough System (ABM Respiratory Care LLC, Eagan, MN), Pegaso Cough (Dima Italia Srl, Bologna, Italy) and CoughAssist T70 (Philips, Inc., Cambridge, MA).

FDA product code: NHJ.

Rationale

Medical policies 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.

OSCILLATORY DEVICES
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 policy.

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.

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 days to 2.8 years

N: number; 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 policy.

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 years (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; N/n: number; NR: not reported; PEP: positive expiratory pressure; Tx: treatment; U.K.: United Kingdom; U.S.: United States; y: year(s).

Table 4. Summary of Key Randomized Controlled Trial Results

Study	N	Number 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		0.007	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; RCT: randomized controlled trial; mo: months.

[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]
Mcllwaine 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. Clinically significant difference not prespecified; 6. Clinically 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	McIlwaine et al. (2013) (2)	Sontag et al. (2010) (3)	Pryor et al. (2010) (4)
Allocation[a]	3. Allocation concealment unclear	3. Allocation concealment unclear	3. Allocation concealment unclear
Blinding[b]	1. Not blinded to treatment assignment	1. Not blinded to treatment assignment	1. Not blinded to treatment assignment
Selective Reporting[c]			
Data Completeness[d]	1. Eighty-eight (82%) of 107 randomized patients completed the trial. Trial limitations were a nearly 20% dropout rate.	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).	1. Ten of 75 randomized patients were lost to follow-up
Power[e]	4. Trial stopped early without enrolling expected number of patients and might have been underpowered to detect clinically significant differences between groups	4. Trial ended earlier than planned	
Statistical[f]			

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 non-inferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
[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 policy.

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.

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; h: hours.

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)	United Kingdom	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)

N/n: number; 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	Number 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	0.002	0.02	0.48

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 to1.0)	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; h: hour; IQR: interquartile range; LCQ: Leicester Cough Questionnaire; N: number; 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-hour 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. Clinically significant difference not prespecified; 6. Clinically 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 Complete-ness[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 treating physician.			3. Power not based on clinically important difference.	
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 non-inferiority 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 policy.

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.

Systematic Reviews

Systematic reviews have evaluated studies of airway clearance techniques in patients with COPD. (10-12) 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 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) Inception or 2011 (CAGR)	28	Participants with investigator-defined COPD, emphysema or chronic bronchitis	907 (5-96)	RCTs (parallel and crossover)	24 hours to >8 weeks
Alghamdi et al. (2020) (13)	Inception to March 2020	8	Patients with COPD	381 (15-120)	RCT and crossover	5 days to 2 years

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 (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. (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	**Comparators**
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; N/n: numbers; NR: not reported; PEP: positive expiratory pressure; Tx: treatment; U.K.: United Kingdom.

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	
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 days)
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. Clinically significant difference not prespecified; 6. Clinically 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	Chakrovorty et al. (2011) (14)	Svenningsen et al. (2016) (15)	Goktalay et al. (2013) (16)	Alghamdi et al. (2023) (13)
Allocation[a]	3. Allocation concealment unclear	3. Allocation concealment unclear	1. Participants not randomly allocated	

			2. Allocation not concealed	
Blinding[b]	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician	1. Not blinded to treatment assignment	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician	1. Not blinded to treatment assignment
Selective Reporting[c]				
Data Completeness[d]	1. High loss to follow-up or missing data: 8 out of 30 withdrew due to COPD exacerbations	1. High loss to follow-up or missing data: 16% withdrew from trial		1. High loss to follow-up or missing data: 15% lost to follow-up and 9% with no follow-up data for objective monitoring
Power[e]	2. Power not calculated for primary outcome	2. Power not calculated for primary outcome	1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference	
Statistical[f]				

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 non-inferiority 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 policy.

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.

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 years with a diagnosis of severe neurologic impairment and respiratory morbidity	Not reported	RCTs and nonrandomized comparative studies	Unclear

N: number; 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 HFCWO 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 HFCWO 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; Caucasian, n=7; Asian, n=4; African American, n=2; Pacific Islander, n=1)	HFCWO (n=12)	Standard chest physical therapy (n=11)
Lange et al. (2006) (19)	U.S.	6	NR	Adults with amyotrophic lateral sclerosis (N=46)	HFCWO (n=22)	No treatment (n=24)

HFCWO: high-frequency chest wall oscillation; n: number; NR: not reported; U.S.: United States.

Table 19. Summary of Key Randomized Controlled Trial Results

Study	Hospitalization/IV Antibiotics	TDI (proportion showing worsening)
Yuan et al. (2010) (18)	N=23	
HFCWO	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; N: number; 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. Clinically significant difference not prespecified; 6. Clinically 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	Yuan et al. (2010) (18)	Lange et al. (2006) (19)
Allocation[a]	1. Allocation concealment unclear	1. Allocation not concealed
Blinding[b]	1. Not blinded to treatment assignment 2. Not blinded outcome assessment (except chest X-rays) 3. Outcome assessed by treating physician	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician
Selective Reporting[c]		
Data Completeness[d]	1. High loss to follow-up or missing data 12% missing data and all in treatment group	1. High loss to follow-up or missing data 15% missing data at 12 weeks
Power[e]	1, 2, 3. Trial was exploratory and was not powered to detect statistically significant findings of the primary outcomes	2. Power not calculated for primary outcome 3. Power not based on clinically important difference

Statistical[f]		

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 HFCWO compared with usual care for the primary outcomes (pulmonary function measures) or most secondary outcomes.

Summary of Evidence

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

For individuals who have bronchiectasis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 reported the clinically important outcomes of exacerbations or hospitalizations. Only 3 RCTs reported on quality of life, and findings were mixed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have 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 17000967 technology results in an improvement in the net health outcome.

For individuals who have respiratory conditions related to neuromuscular disorders who receive oscillatory devices, the evidence includes 2 RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. One of the RCTs was not powered to detect statistically significant differences. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvements after high-frequency chest wall compression devices versus usual care in primary outcomes, in pulmonary function measures, or in most secondary outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In 2008, clinical input indicated that the available studies demonstrated that these oscillatory devices are comparable with chest physical therapy for CF 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. The clinical input did not support using oscillatory devices for treatment of chronic obstructive pulmonary disease.

Practice Guidelines and Position Statements
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).

Ongoing and Unpublished Clinical Trials

Some currently ongoing and completed trials that might influence this policy are listed in Table 22.

Table 22. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
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
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
NCT04271969	Clinical Effectiveness Of High Frequency Chest Wall Oscillation (HFCWO) In A Bronchiectasis Population	125	Dec 2023

NCT: national clinical trial.

MECHANICAL INSUFFLATION-EXSUFFLATION DEVICES

The coverage statement related to mechanical insufflation-exsufflation device is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services (CMS). (23)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	94669
HCPCS Codes	A7020, A7025, A7026, E0480, E0481, E0482, E0483, E0484, S8185

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/01/2025	Document updated with literature review. The following changes were made to Coverage: 1) Completely revised conditional criteria for oscillatory devices; 2) Revised conditional criteria for mechanical insufflation-exsufflation devices to be consistent with coverage guidance from the centers for Medicare and Medicaid Services; 3) Removed NOTEs 2-4; 4) Removed experimental, investigational and/or unproven statement related

	to all other types of airway clearance devices; and 4) Removed not medically necessary statement on device replacements or upgrades. Added references 13 and 23; others removed.
10/01/2024	Document updated with literature review. The following change was made to Coverage: Modified the following statement "All other types and uses of airway clearance devices are considered experimental, investigational and/or unproven, including but not limited to, the Volara™ System oscillation and lung expansion (OLE) therapy device**."** Added references 27 and 28.
08/15/2024	Reviewed. No changes.
04/15/2023	Document updated with literature review. The following change was made to the Coverage section: Removed "who require ventilatory assistance" from the mechanical insufflation-exsufflation devices medically necessary criteria. Added references 9 and 20.
01/15/2023	Reviewed. No changes.
09/15/2021	Document updated with literature review. The following change was made to the Coverage section: NOTE 4 was added to the mechanical insufflation-exsufflation devices non-medical necessity language. References 1 and 11 were added.
03/01/2020	Document updated with literature review. The following statement was added to the Coverage section: Airway clearance device replacements or upgrades are considered not medically necessary when requested for convenience or to upgrade to newer technology when the current components remain functional. References 5, 8, and 19-22 were added.
10/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Product names were removed from the coverage section. Coverage unchanged.
07/01/2015	Reviewed. No changes.
10/15/2014	Document updated with literature review. The following was removed from the coverage statement for mechanical insufflation–exsufflation devices: "(a peak cough expiratory flow of less than 2-3L per second)." In addition, the following clarifying statements were added : High-frequency chest wall compression devices and IPV devices used solely as an alternative to CPT for conditions other than those specified in the medically necessary statements above are considered not medically necessary, was changed to the following: Use of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices as an alternative to chest physical therapy is considered not medically necessary unless CPT is contraindicated, ineffective, not tolerated, or unavailable. Use of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices for treating lung diseases other than those listed in the policy, such as chronic obstructive pulmonary disease (COPD), is considered experimental, investigational and /or unproven.

01/01/2011	Document updated with literature review. Two medical documents (DME101.027, Oscillatory Devices for the Treatment of Cystic Fibrosis (CF) and Other Lung Disorders and DME104.042, Mechanical Insufflation-Exsufflation as an Expiratory Muscle Aid) were combined into this medical document, and the title of this medical document was changed to Airway Clearance Devices.
07/15/2010	Document updated with literature review. Coverage has been changed: 1) IPV devices may be considered medically necessary for patients with CF or bronchiectasis when criteria are met. 2) High-frequency chest wall compression devices may be considered medically necessary in neuro-muscular diseases when criteria are met.
02/15/2009	Revised/updated entire document.
10/01/2008	Revised updated entire document. This policy is no longer scheduled for routine literature review and update.
06/01/2007	Revised/updated entire document
12/15/2006	Revised/updated entire document
04/01/2003	CPT/HCPCS code(s) updated
03/01/2003	Revised/updated entire document
01/01/2000	CPT/HCPCS code(s) updated
04/01/1999	Revised/updated entire document
02/01/1997	Revised/updated entire document
05/01/1996	CPT/HCPCS code(s) updated
07/01/1995	Revised/updated entire document
04/01/1993	CPT/HCPCS code(s) updated
01/01/1993	New medical document