Health Evidence Review Commission (HERC)

Coverage Guidance: High-Frequency Chest Wall Oscillation Devices

Approved 8/11/2022

HERC Coverage Guidance

High-frequency chest wall oscillation devices are recommended for coverage for patients with cystic fibrosis (*weak recommendation*) when there is documentation of frequent exacerbations requiring antibiotics, frequent hospitalization, or rapidly declining lung function measured by spirometry, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis *(weak recommendation)* when the 3 criteria below are met:

A) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
B) The patient has experienced either:
    1) Daily productive cough for at least 6 continuous months, OR
    2) Frequent (> 2 times a year) exacerbations requiring antibiotic therapy, *AND*
C) The patient has received mucolytics and less costly airway clearance treatments (for example, chest physiotherapy, positive expiratory pressure therapy, self-management techniques) OR such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (*weak recommendation*) when there is evidence of chronic lung infection, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are not recommended for coverage for patients with chronic obstructive pulmonary disease *(weak recommendation)*.

Note. Definitions for strength of recommendation are in Appendix A, GRADE Table Element Descriptions. Rationales for each recommendation appear below in the GRADE table.

Oregon Health Authority

Table of Contents

Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

The Health Evidence Review Commission (HERC) uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence considering all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

GRADE Tables

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	Compared to chest physiotherapy: No significant difference in mean days of hospitalization (mean difference, -0.20; 95% CI, -2.32 to 1.92; *P* > .05). ●○○○ *(very low confidence, based on 1 RCT, n = 50)*	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and	Some patients may not be able to tolerate chest physiotherapy or positive expiratory pressure devices.
Mortality *(Critical outcome)*	No evidence			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Mixed results <u>Compared to positive expiratory pressure</u>: Significantly more exacerbations requiring antibiotics (median, 2.0; interquartile range, 1.0 to 3.0) than the positive expiratory pressure therapy group (median, 1.14; interquartile range, 0.0 to 2.0; odds ratio, 4.10; 95% CI, 1.42 to 11.84; *P* = .007) No significant difference when limited to IV antibiotics (OR, 2.36; 95% CI, 0.81 to 6.94) ●○○○ *(very low confidence, based on 1 RCT, n = 107)* <u>Compared to chest physiotherapy</u>: No significant difference in time to pulmonary exacerbation requiring antibiotics (*P* > .05). ●○○○ *(very low confidence, based on 1 RCT, n = 115)* <u>Compared to other oral or external oscillatory devices</u>: No significant difference ●○○○ *(very low confidence, based on 1 RCT, n = 16)*	However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations. Chest physiotherapy must be provided by a trained caregiver for 20 to 40 minutes, one or more times per day; could be provided by a paid or unpaid caregiver.	consistent treatment.	Some patients may not have caregivers who are available or physically able to administer daily chest physiotherapy.
Exercise Capacity *(Important outcome)*	No evidence			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Breathlessness or Cough *(Important outcome)*	No evidence			

Balance of benefits and harms: Based on very low-confidence evidence, high-frequency chest wall oscillation devices have similar outcomes to chest physiotherapy for reducing hospitalizations. There is mixed evidence compared to positive expiratory pressure, chest physiotherapy, and other oscillating devices for reducing exacerbations in patients with cystic fibrosis. There are few device-related harms found for high-frequency chest wall oscillation devices.
Rationale: High-frequency chest wall oscillation devices are not inferior to other alternatives based on very low certainty evidence, and have a low rate of device-related harms, but much higher cost. However, we recommend coverage because some patients may need other treatment options and due to the small size of the population affected. The recommendation is weak because of the very low quality of the evidence.
Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with cystic fibrosis (*weak recommendation)* when there is documentation of frequent severe exacerbations requiring antibiotics and/or hospitalization, despite either: a) having received chest physiotherapy and positive expiratory pressure therapy, OR b) documentation that chest physical therapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. CI: confidence interval; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	No evidence	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment.	Appointed expert opinion supported coverage of high-frequency chest wall oscillation devices for bronchiectasis, due to the pathophysiologic similarities of this condition to cystic fibrosis bronchiectasis, but only when there is evidence of chronic infection.
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Respin11 HFCWO device compared to standard pharmacological therapy alone: Significantly fewer exacerbations over 12 months on average for 1 group that used high-frequency chest wall oscillation devices: • Respin11 group (mean, 0.52 exacerbations; SD, 0.14) • Pharmacological therapy with other device-delivered interventions (mean, 0.96 exacerbations; SD, 0.40) • Between-group difference, $P < .001$ SmartVest HFCWO device compared to standard pharmacological therapy alone: The treatment group that used the SmartVest HFCWO device did not have significantly fewer exacerbations when compared to the group that received standard pharmacological therapy • SmartVest group (mean, not reported; SD, not reported) • Pharmacological therapy with other device-delivered interventions (mean, 0.96 exacerbations; SD, 0.40) • Between-group difference, $P > .05$ ●○○○ *(very low confidence, based on 1 RCT, n = 42)*			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Exercise Capacity *(Important outcome)*	No evidence			
Breathlessness or Cough *(Important outcome)*	Compared to chest physiotherapy: Significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale (mean difference, -5.8; 95% CI, -7.21 to -4.39; N = 20; *P* < .05) ●○○○ *(very low confidence, based on 1 RCT, n = 20)* Respin11 HFCWO device compared to standard pharmacological therapy alone: Significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale: • Respin11 group (mean at 12 months post-baseline, 2.8; SD, not reported) • Pharmacological therapy with other device-delivered interventions group (mean at 12 months post-baseline, 6.1; SD, not reported) • Between-group difference, *P* < .001 ●○○○ *(very low confidence, based on 1 RCT, n = 42)* SmartVest HFCWO device compared to standard pharmacological therapy alone: The treatment group that used the SmartVest high-frequency chest wall oscillation device did not demonstrate a significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale: • SmartVest group (mean at 12 months post-baseline, 4.5; SD, not reported)			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
	• Pharmacological therapy with other device-delivered interventions group (mean at 12 months post-baseline, 6.1; SD, not reported) • Between-group difference, *P* > .05 ●○○○ *(very low confidence, based on 1 RCT, n = 42)*			

Balance of benefits and harms: There is very low confidence evidence that high-frequency chest wall oscillation devices improve key outcomes for patients with non-cystic fibrosis bronchiectasis. However, expert opinion supports use in this population based on data extrapolated from cystic fibrosis, which is a similar condition, but only when there is evidence of chronic airway infection or chronic daily cough. There are few device-related harms to high-frequency chest wall oscillation devices.
Rationale: The evidence is equivocal regarding whether high-frequency chest wall oscillation improves outcomes for patients with non-cystic fibrosis bronchiectasis, but we recommend coverage of these devices based on low risk of harms and the fact that they may result in cost offsets if they prevent hospitalizations. Expert testimony that pathophysiologic reasoning makes extrapolating evidence from the cystic fibrosis population reasonable. The recommendation is weak because of our very low confidence in the available evidence.
Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis (*weak recommendation*) when the 3 criteria below are met: A) The bronchiectasis is confirmed by computed tomography (CT) scan, *AND* B) The patient has experienced either: 1. Daily productive cough for at least 6 continuous months, *OR* 2. Frequent (> 2 times a year) exacerbations requiring antibiotic therapy, *AND* C) The patient has received mucolytics and less costly airway clearance treatments (for example, chest physiotherapy, positive expiratory pressure therapy, self-management techniques) OR such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. CI: confidence interval; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial; SD: standard deviation.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with chronic obstructive pulmonary disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	No evidence	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment.	Appointed expert did not recommend high-frequency chest wall oscillation devices for this population.
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	No evidence			
Exercise Capacity *(Important outcome)*	No evidence			
Breathlessness or Cough *(Important outcome)*	Compared to standard pharmacological therapy without oscillatory devices: Significantly greater improvement on the 12-point Breathlessness Cough Sputum Score scale over 4 weeks: • The Vest Airway Clearance System Model 205 group (baseline mean, 6.6; SD, 2.8; post-treatment mean, 5.2; SD, 2.2) • Standard pharmacological therapy group (baseline mean, 4.6; SD, 1.7; post-treatment mean, 5.5; SD, 2.1) • Between-group difference, *P* = .007 ●○○○ *(very low confidence, based on 1 RCT, n = 40)*			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with chronic obstructive pulmonary disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
	Compared to intrapulmonary percussive ventilation: Significantly less improvement on the 12-point Breathlessness Cough Sputum Score scale over 4 weeks: • The Vest Airway Clearance System Model 205 group (baseline mean, 6.6; SD, 2.8; post-treatment mean, 5.2; SD, 2.2) • Intrapulmonary percussive ventilation group (baseline mean, 6.3; SD, 1.4; post-treatment mean, 3.1; SD, 1.7) • Between-group difference, $P < .01$ ●○○○ *(very low confidence, based on 1 RCT, n = 40)*			

Balance of benefits and harms: There is insufficient evidence that high-frequency chest wall oscillation devices improve key outcomes for patients with chronic obstructive pulmonary disease compared to alternatives. Expert opinion does not recommend use in this population. There are few device-related harms to high-frequency chest wall oscillation devices.
Rationale: There is insufficient comparative evidence of benefit for this indication. It is a weak recommendation because of our very low confidence in the evidence.
Recommendation: High-frequency chest wall oscillation devices are not recommended for coverage for children and adults with chronic obstructive pulmonary disease *(weak recommendation).*

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial; SD: standard deviation.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with pulmonary complications from neuromuscular disease resulting in chronic lung disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	Compared to standard chest physiotherapy (pediatric patients with neuromuscular disease): There was a nonsignificant difference in the number of control group participants requiring hospitalizations (2/7) compared to the HFCWO device group (0/7; *P* > .05) ●○○○ *(very low confidence, based on 1 RCT, n = 14)*	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment. This group of conditions varies widely in severity and patients may have different preferences based on their condition.	Neuromuscular diseases are a broad range of conditions with very different pulmonary involvement. Many of these conditions have populations that are too small to meaningfully study. Appointed expert recommendation was for use in patients with neuromuscular disease who have evidence of chronic airway infection (defined as persistent culture positivity of organisms known to
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Compared to standard chest physiotherapy (pediatric patients with neuromuscular disease): There was nonsignificant difference between control group participants requiring antibiotics (3/7) compared to the HFCWO device group (2/7; *P* > .05) ●○○○ *(very low confidence, based on 1 RCT, n = 14)*			
Exercise Capacity *(Important outcome)*	No evidence			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with pulmonary complications from neuromuscular disease resulting in chronic lung disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Breathlessness or Cough *(Important outcome)*	Compared to no treatment (adult patients with ALS): Significantly greater improvement in breathlessness (high-frequency chest wall oscillation group mean difference, -1.28; untreated group mean difference, 0.84; *P* < .05) Compared to no treatment (adult patients with ALS): No statistically significant differences in day or night cough or dyspnea ●○○○ *(very low confidence, based on 1 RCT, n = 35)*	the extent that it reduces hospitalizations and exacerbations.		cause respiratory infection).

Balance of benefits and harms: There is no evidence that high-frequency chest wall oscillation devices improve key outcomes compared to standard treatments for patients with neuromuscular disease resulting in chronic lung disease. Expert testimony indicates patients with neuromuscular conditions and evidence of chronic airway infection benefit from these devices. There are few device-related harms to high-frequency chest wall oscillation devices.
Rationale: There is insufficient comparative evidence of benefit for this population, but based on expert opinion and the potential to reduce exacerbations/costs, we recommend coverage for patients with neuromuscular disease when there is evidence of chronic airway infection. The disparate types of diseases and small populations within each disease make high-quality studies difficult to conduct and are not anticipated to be forthcoming. The recommendation is weak because of our very low confidence in the available evidence.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with pulmonary complications from neuromuscular disease resulting in chronic lung disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (*weak recommendation)* when there is evidence of chronic lung infection, despite either: a) having received chest physiotherapy and positive expiratory pressure therapy, OR b) documentation that such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).				

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Abbreviations. ALS: amyotrophic lateral sclerosis; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial.

Background

Individuals with impaired airway clearance are unable to effectively clear mucus from their airways.[1] High-frequency chest wall oscillation (HFCWO) devices are designed to help those with impaired airway clearance clear mucus from their airways. Impaired airway clearance can be a characteristic of several respiratory disorders and neuromuscular diseases, including:

- Chronic obstructive pulmonary disorder (COPD)
- Cystic fibrosis
- Bronchiectasis, which is characterized by chronic cough, bronchial wall thickening, permanent expansion of the airway, and overproduction of thick mucus
- Multiple sclerosis
- Muscular dystrophy
- Spinal muscular atrophy
- Amyotrophic lateral sclerosis (ALS)

The Centers for Disease Control and Prevention estimate that 35,000 individuals have been diagnosed with cystic fibrosis in the US, and 16 million US individuals are living with COPD.[2,3] According to a claims-data analysis using information from 2013, aproximately 340,000 to 522,000 adults receive treatment for bronchiectasis in the US, and about half of patients diagnosed with bronichiectasis have comorbid COPD.[4]

Failing to adequately and regularly clear mucus from the airways can result in exacerbations and worsening of chronic lung disease that require antibiotic treatment, hospitalization and other interventions.[5] Therefore, a key element of managing these diseases is to keep airways clear of excess secretions. When patients are unable to mobilize mucus secretions on their own, airway clearance techniques for patients with many respiratory disorders can include:

- Chest physiotherapy
    - Can be administered by respiratory therapists, family members, or other informal caregivers
    - Has been the standard of care for first-line secretion clearance for individuals with excessive or retained mucus.[6]
    - Typically administered by a trained caregiver over 1 to 3 sessions per day, each lasting 20 to 30 minutes, depending on disease severity.[6]
    - May also be known as percussion and postural drainage.
- Breathing techniques
    - Typically taught to patients by pulmonary rehabilitation professionals.
    - Active cycle breathing techniques include breathing control, thoracic expansion exercises, and the forced expiration technique.[6]
    - Autogenic drainage involves breathing techniques in 3 phases (unstick, collect, and evacuate) at different lung volumes.
    - Breathing techniques do not require devices or assistance and can be self-administered.[6]
- Positive expiratory pressure devices
    - Increase resistance, prevent airway closure, and increase collateral ventilation.[6]

    - Some use oscillatory mechanisms to create vibrations when a patient breathes out.[6]
    - Examples include TheraPEP, Resistex PEP mask, Pari RC Cornet Mucus Clearing Device, Flutter, Acapella, Quake, and Aerobika.
    - The therapy from these devices can be self-administered without assistance.[6]
- Intrapulmonary percussive ventilation
    - A pneumatic device that uses high-frequency oscillatory ventilation through a mouthpiece.[6]
    - An example is the Percussionaire Corporation IPV Ventilator.[6]
- High-frequency chest wall oscillation (HFCWO) devices, which are described in the following section of this document.
    - Therapy from these devices can be self-administered.[6]

Indications

Children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease might be prescribed HFCWO devices to assist in the clearance of mucus in airways as part of their treatment plan. HFCWO devices exert external force on the chest wall to assist in mobilizing mucus and use sound waves or pressure from inflation and deflation at variable intensities and frequencies to generate the force. They are much more expensive than the alternative forms of treatment but require less time from caregivers than chest physiotherapy.

Technology Description

We identified 1 nonwearable HFCWO device and 5 wearable HFCWO devices that are currently approved by the US Food and Drug Administration (FDA) and being manufactured for use in children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease. See Table 1 for a description of each device.

Table 1. HFCWO Device Descriptions

Device Name FDA Approval Date	Manufacturer	Features	Indications
Frequencer V2 and V2x[7] January 26, 2011[8]	Dymedso	• Portable • Not wearable • 4 sizes of adaptors for patients of different sizes • Generates low frequency sound waves within the range of 20-65 Hz and offers an adjustable intensity based on the patient's condition	• Cystic fibrosis • Chronic bronchitis • COPD • Bronchiectasis • Ciliary dyskinesia syndromes • Asthma • Muscular dystrophy • Neuromuscular degenerative disorder • Post-operative atelectasis • Thoracic wall defects

Device Name FDA Approval Date	Manufacturer	Features	Indications
SmartVest SQL System[9] December 19, 2013[10]	Electromed	• Portable • Wearable • 8 different sizes • 16 pounds • Quiet (60 decibels) • 91% decompression (greater percent decompression than other vests) • Wireless capabilities that can connect usage to personal reports or to healthcare provider records	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions
The Vest Airway Clearance System Model 105[11] February 21, 2003[12]	Hill-Rom	• Portable • Wearable • 4 styles of garment for different body types (full garment, wrap garment, chest garment, C3 garment) • 17 pounds • Multiple programing options, including several languages • Can program a reminder to cough • Vest covers are washable and dryable • Offers at-home training • Wireless capabilities that can connect usage to personal reports or to healthcare provider records	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions • Primary ciliary dyskinesia • Post lung transplant • Spinal cord injury

Device Name FDA Approval Date	Manufacturer	Features	Indications
Respin11[13] July 13, 2012[14]	RespInnovation SAS	• Portable • Wearable • Vest plus control unit weight 11 kilograms • Several sizes for different sizes • Can target specific chest areas • Programmable with several protocols • Uses an air pressure piston which inflates and completely empties each cycle enabling the patient to breathe, speak and cough without restriction • Does not provide constant background pressure which manufacturer claims makes the therapy easy to tolerate and puts no pressure onto the patient's physiological state	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions • Emphysema
InCourage Vest[15] June 17, 2005[16]	Philips, via RespirTech	• Portable • Wearable • 17.5 pounds • Several sizes for different ages • Uses triangular waveform technology that manufacturer claims delivers a chest physiotherapy-like "thump" to the chest • Offers at-home training	• Bronchiectasis • COPD • Cystic fibrosis • Certain neuromuscular conditions
AffloVest[17] March 27, 2013[12]	International Biophysics Corporation	• Portable • Wearable • Available in 7 sizes • Battery-operated • Has eight mechanical oscillating motors that target all 5 lobes of the lungs, front and back, for fully mobile use • Programmable settings	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular diseases

Device Name FDA Approval Date	Manufacturer	Features	Indications
		• Advertised as the lightest vest option (no weight specified)	

Abbreviations. COPD: chronic obstructive pulmonary disorder; FDA: US Food and Drug Administration; HFCWO: high-frequency chest wall oscillation.

Evidence Review

We identified 2 systematic reviews,[6,18] 4 randomized controlled trials (RCTs),[19-21,44] and a single ongoing RCT[22] for the comparative effectiveness of HFCWO devices for children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease. We did not identify any studies of the comparative cost effectiveness of HFCWO devices.

Cystic Fibrosis

We identified a single systematic review that focused on airway clearance techniques in people diagnosed with cystic fibrosis, and included RCTs and quasi-randomized trials of HFCWO devices.[6] The review included external chest oscillating devices as well as oral oscillatory devices.[6] Morrison and colleagues abstracted information related to the scope of this coverage guidance: exercise tolerance and frequency of exacerbations with or without hospitalization.[6] Morrison and colleagues included 39 studies in the qualitative review and 19 studies in meta-analyses; they rated 85% of these studies as having unclear risk of bias.[6] They rated the quality of evidence summarized in the review as very low to low across outcomes.[6] We rated this systematic review as having low risk of bias, and the authors rated component studies as having unclear to high risk of bias.

The studies in this review did not report symptoms of breathlessness or cough, mortality, or exercise capacity for participants using HFCWO devices.

Exacerbations and Hospitalizations

The single RCT (N = 107) that compared HFCWO devices to positive expiratory pressure therapy reported that the average number of exacerbations requiring antibiotics during the 12-month study period was significantly higher in the HFCWO groups (median, 2.0; interquartile range, 1.0 to 3.0) than the positive expiratory pressure therapy group (median, 1.14; interquartile range, 0.0 to 2.0; Odds Ratio [OR] 4.10; 95% CI, 1.42 to 11.84; *P* = .007).[6] However, this result was no longer significant when limited to exacerbations requiring treatment with intravenous antibiotics (OR, 2.36; 95% CI, 0.81 to 6.94, *P* > .05).[6]

Two RCTs compared HFCWO devices to conventional physiotherapy for patients with cystic fibrosis. In 1 RCT (N = 50) of patients with cystic fibrosis admitted to a hospital for an acute exacerbation, there was no significant difference between the study groups for days of hospitalization (mean difference, -0.20; 95% CI, -2.32 to 1.92).[6] The participants in this study were between 16 and 25 years of age, and 64.0% were identified as male.[6] Patients in the conventional physiotherapy group received therapy from a respiratory physiotherapist 3 times per day for approximately 30 minutes each time, along with the use of an inhaler prior to sessions with the physiotherapist.[6] The second RCT (N = 115) reported no

significant between-group difference in time to pulmonary exacerbations requiring antibiotics in children, adolescents, and adults with cystic fibrosis.[6]

Neither of the 2 RCTs that compared HFCWO devices to breathing techniques for cystic fibrosis reported exacerbations or any other outcome scoped for this review.[6]

Only 1 of 6 studies comparing HFCWO devices to other external and oral oscillatory devices assessed exacerbations (N = 16); it reported that there were no significant differences between groups for use of home intravenous therapies.[6]

Bronchiectasis

We identified a single systematic review focused on airway clearance techniques for people diagnosed with bronchiectasis,[18] and a single RCT (Nicollini et al., 2020; N = 60) that was published after the search dates of the systematic review.[19] We rated the systematic review as having a low risk of bias and the RCT as having a moderate risk of bias. The systematic review included 7 RCTs, but only 1 included RCT used HFCWO devices in the intervention group (Nicollini et al., 2013; N = 30).[23] This RCT was rated as having an unclear risk of bias by the authors of the systematic review. Both RCTs focused on adults.[19,23] Neither of these RCTs reported on mortality.

Exacerbations and Hospitalizations

In Nicollini and colleagues' 2020 RCT, both groups that used HFCWO devices had statistically significant improvement in exacerbations during the 12 months of the study compared to the average exacerbations per year prior to baseline.[19] Only the group that used the Respin11 HFCWO device had significantly fewer exacerbations during the 12-month study period, compared to the pharmacological comparison group that only received standard pharmacological care without HFCWO or chest physiotherapy (Respin11: mean, 0.52; standard deviation [SD], 0.14; control: mean, 0.96; SD, 0.40; between-group difference: $P < .001$).[19] The 2 HFCWO devices included in this study are described in Table 1.

Breathlessness or Cough

Nicollini and colleagues' 2013 RCT, identified in the systematic review, reported a statistically significant decrease in breathlessness, cough and sputum on the Breathlessness, Cough, and Sputum Scale (BCSS) in the group treated with HFCWO devices compared to a control group that received chest physiotherapy (mean difference, -5.8; 95% CI, -7.21 to -4.39; N = 20; $P < .05$).[23] This study summed the scores of items across 3 subscales, which makes it challenging to anchor this improvement in patient-response terms; publications that assess the clinical importance of change-scores for this scale rely on reporting the average score across subscales (i.e., mean-scores range from 0 to 4, and sum-scores range from 0 to 12 on this scale). This RCT also reported that use of HFCWO devices was associated with lower scores on a dyspnea scale compared to the group that received chest physiotherapy (mean difference, -1.7; 95% CI, -2.4 to -1; N = 20; $P < .05$). [23]

The additional Nicollini and colleagues' 2020 RCT also reported that the group using the Respin11 HFCWO device demonstrated statistically significant improvement on the BCSS compared to the control group that received pharmacological therapy and standard care without HFCWO (Respin11 mean at 12 months post-baseline, 2.8; SD, not reported; control mean at 12 months post-baseline, 6.1; SD, not reported*; P* < .001).19 The group that used the SmartVest HFCWO device did not demonstrate a

significant improvement on the BCSS compared to the control group (SmartVest mean at 12 months post-baseline, 4.5; SD, not reported; control mean at 12 months post-baseline, 6.1; SD, not reported; $P > .05$).

Exercise Capacity

The Nicollini and colleagues' 2020 RCT used a 6-minute walk test to assess exercise capacity but did not report the results of the walk test.[19]

COPD

We identified a single RCT that reported on the safety and effectiveness of HFCWO devices compared to intrapulmonary percussive ventilation in patients with severe COPD, and rated this RCT as having a moderate risk of bias.[20] The listed authors overlapped with the 2 RCTs reviewed in the bronchiectasis section, and the design of all 3 RCTs was similar.[20] Participants in this study had severe or very severe (but stable) COPD and were followed for 4 weeks after being randomized into 3 groups: 1 group received 2 sessions per day (lasting 15 minutes per session) of intrapulmonary percussive ventilation with a respiratory physiotherapist using a percussive ventilator; 1 group received 2 sessions per day (lasting 20 minutes per session) of HFCWO with a respiratory physiotherapy; and 1 group received standard pharmacological therapy alone that the investigators termed "the best medical therapy."[20] Most participants were 70 years or older and had more than 2 exacerbations and 1 hospitalization per year.[20] This study did not report mortality, hospitalizations, exacerbations, or exercise capacity.[20]

Breathlessness or Cough

The average BCSS score for participants in the control group worsened over time, but average BCSS scores for participants in the intrapulmonary percussive ventilation and HFCWO groups improved; both treatment groups had statistically significantly lower BCSS scores when compared to the standard treatment group (control group baseline mean, 4.6; SD, 1.7; control group post-treatment mean, 5.5; SD, 2.1).[20] Symptoms were nearly halved in the group receiving intrapulmonary percussive ventilation (intrapulmonary percussive ventilation group baseline mean, 6.3; SD, 1.4; intrapulmonary percussive ventilation group post-treatment mean, 3.1; SD, 1.7).[20] The intrapulmonary percussive ventilation group BCSS scores were statistically significantly lower than HFCWO group scores after the 4 weeks of treatment (HFCWO group baseline mean, 6.6; SD, 2.8; HFCWO group post-treatment mean, 5.2; SD, 2.2; between-group difference, $P < .01$).[20] In other words, the participants in the intrapulmonary percussive ventilation group improved more on symptoms of breathlessness or cough on average, compared to participants who received HFCWO device therapy.

Pulmonary Complications from Neuromuscular Disease

We identified 2 RCTs that assessed the safety and effectiveness of HFCWO devices for individuals diagnosed with a neuromuscular disease with pulmonary complications.[21,44] One RCT focused on adults diagnosed with ALS.[21] Participants in this study were followed for 12 weeks after being randomized into groups that received HFCWO therapy (N = 19) or no treatment (N = 16).[21] We rated this RCT as having a high risk of bias. This study did not report mortality, exacerbations, hospitalizations, or exercise capacity.

The second RCT included 14 children various neuromuscular diseases (i.e., Duchenne muscular dystrophy, unown mitochondrial myopathy, congenital muscular dystrophy, mitochondrial thymidine

kinase 2 deficiency, spinal muscular atrophy type 2, muscle-eye-brain disease, and giant axonal neuropathy).[44] None of the participating children had used cough-assistive devices or intrapulmonary percussive ventilation prior to the trial, but 10 relied on nocturnal noninvasive bilevel ventilation and 1 was dependent on a ventilator.[44] Participants were randomized to receive standard chest physiotherapy (N = 7) or to receive HFCWO device therapy (N = 7) for a mean of 5 months; follow-up periods varied nonsignificantly by participant and group assignment.[44] An additional 9 participants in this RCT were diagnosed with cerebral palsey, but did not have neuromuscular disease diagnoses;[44] we report outcomes from this study when the results were reported separately for participants with cerbral palsey and participants with neuromuscular disease (i.e., pulmonary exacerbations and hospitalizations). We rated this study as having a high risk of bias.

Exacerbations and Hospitalizations

The RCT that included children with neuromuscular disease reported hospitalization and pulmonary exacerbations that required antibiotics. There was a nonsignificant difference in the number of control group participants requiring hospitalizations (2/7) compared to the HFCWO device group (0/7; $P > .05$), and nonsignificant difference between control group participants requiring antibiotics (3/7) compared to the HFCWO device group (2/7; $P > .05$).[44]

Breathlessness or Cough

On average, participants in the HFCWO device group had a statistically significantly greater decrease in breathlessness (HFCWO group mean difference, -1.28; group receiving no care mean difference, 0.84; $P < .05$) in the RCT that included adults with ALS, but no statistically significant differences in day or night cough or dyspnea.[21] Among the 21 participants with impaired lung capacity (forced vital capacity of 40% to 70%) in this RCT, this pattern of improvement in breathlessness for participants using HFCWO devices was further accentuated (HFCWO group mean difference, -1.71; untreated group mean difference, 1.51; $P < .05$).[21]

Harms of HFCWO Devices

We reviewed the RCTs described above for information about device-related harms and adverse events. We also searched the FDA's manufacturer and user facility device experience database (MAUDE) for reports of adverse events for each of the HFCWO devices listed in the technology description.

A single RCT comparing HFCWO devices to positive expiratory pressure therapy for patients with cystic fibrosis reported adverse events.[24] This RCT was included in the systematic review described in the cystic fibrosis section, and used the inCourage System from RespirTech for the HFCWO device.[6,24] The authors for this RCT reported that the number of adverse events was not statistically different between the 2 groups (HFCWO, 200 events; positive expiratory pressure, 163 events; $P > .05$).[23] However, the HFCWO device group had significantly more lower airway adverse events (mean, 2.46; SD, not reported) compared to the positive expiratory pressure group (mean, 1.72; SD not reported; $P = .023$).[24] Lower airway events included increased cough, chest infection, hemoptysis, decreased lung function and chest pain.[24]

Reports identified in the MAUDE database are listed in Table 2, by device.

Table 2. Adverse Events Reported in MAUDE by HFCWO Device

Device Name FDA Approval Date	Manufacturer	Adverse Event(s)
Frequencer V2 and V2x[7] January 26, 2011[8]	Dymedso	• No records
SmartVest SQL System[9] December 19, 2013[10]	Electromed	• No records
The Vest Airway Clearance System Model 105[11] February 21, 2003[12]	Hill-Rom	• No records
Respin11[13] July 13, 2012[14]	RespInnovation SAS	• No records
InCourage Vest[15] June 17, 2005[16]	Philips, via RespirTech	• 8 reports identified classified under injury event type ○ Rib bone fractures in 3 different patients ○ 1 vertebral fracture ○ 1 electromagnetic interference problem with a pacemaker ○ 1 hematoma ○ 1 pneumothorax ○ 1 pressure problem with co-occurring mastitis
AffloVest[17] March 27, 2013[12]	International Biophysics Corporation	• 1 report identified • Fractured ribs

Abbreviations. FDA: US Food and Drug Administration; HFCWO: high-frequency chest wall oscillation; MAUDE: manufacturer and user facility device experience database.

Comparative Cost Effectiveness of HFCWO Devices

We did not identify any comparative cost-effectiveness studies of HFCWO devices.

Ongoing Studies for HFCWO Devices

We identified a single ongoing comparative study for HFCWO devices in the Clinical Trials Registry. This pilot study will evaluate the use of the Vest system for treatment of bronchiectasis patients in the home setting.[25] This study is a nonblinded, multi-site, randomized controlled trial that anticipates enrolling 70 participants, and will compare the Vest HFCWO therapy to oscillating positive expiratory pressure (OPEP) therapy for adults aged 18 years and older diagnosed with bronchiectasis.[25] Assessed outcomes will include pulmonary exacerbations and quality of life.[25] The anticipated study completion date was November 2020.[25]

Evidence Summary

For patients with cystic fibrosis, we have very low confidence that HCWFO device therapy is equivalent to conventional chest physiotherapy for reducing hospitalizations. There is mixed evidence for

prevention of exacerbations requiring antibiotics compared to positive expiratory pressure, conventional chest physiotherapy, and other oscillating devices. There is no evidence regarding other outcomes.

For patients with bronchiectasis, we have very low confidence that HFCWO device therapy reduces hospitalizations from exacerbations and improves symptoms of breathlessness and cough compared to pharmacological therapy with other device-delivered interventions (e.g., positive expiratory pressure mask), and compared to pharmacological therapy without other devices. There is no evidence regarding other outcomes.

For patients with COPD, we have very low confidence that HFCWO device therapy is associated with less improvement in breathlessness and cough compared to intrapulmonary percussive ventilation. There is no evidence regarding other outcomes.

For patients with pulmonary complications from neuromuscular disease, we have very low confidence that HFCWO device therapy improves symptoms of breathlessness compared to no treatment or to standard chest physiotherapy. One study only included patients with ALS receiving HFCWO devices compared to no treatment, and the study that included children with neuromuscular disease likely had too few participants to identify whether there was a benefit to using HFCWO devices compared to standard chest physiotherapy. We have very low confidence that HFCWO device therapy does not improve day or night cough, or dyspnea compared to receiving no treatment for patients with ALS. There is no evidence regarding other outcomes for other neuromuscular diseases resulting in chronic lung disease.

We identified few reports of adverse events or device-related harms of HFCWO devices in the reviewed studies and the FDA's database for adverse event reporting for devices.

Policy Landscape

Payer Coverage Policies

We identified HFCWO device coverage policies for Washington State's Medicaid program, a local coverage determination from Medicare, and 4 private payers. Medicare's local coverage determination and all 4 private payer policies require documentation that standard treatments, such as chest physiotherapy, have failed or are not tolerated before covering HFCWO devices; these policies cover HFCWO devices for patients with cystic fibrosis and bronchiectasis, but coverage for neuromuscular diseases with pulmonary complications varies. None of these policies cover HFCWO devices for patients with COPD except when there is comorbid bronchiectasis.

Medicaid

The Washington Health Care Authority's (HCA) policy for respiratory care considers chest physiotherapy to be the standard of care for secretion clearance, but states that there are situations in which conventional chest physiotherapy is unavailable, ineffective, or not tolerated.[26] The HCA covers HFCWO air-pulse generator systems when medically necessary for a person with a diagnosis characterized by excessive mucus production and difficulty clearing secretions.[26] Other airway-clearance devices covered by the HCA include mechanical percussors, oscillatory positive expiratory pressure devices, positive expiratory pressure devices, and cough stimulating devices, including alternating positive and negative

airway pressure devices, and replacement batteries.[26] Prior authorization is required, and the policy also states that the rental of a HFCWO device and generator includes all repairs and replacements, and that the manufacturer will replace the vest according to changes in user's size during the rental and purchase period.[26] The HFCWO device is considered to be purchased after 12 months of rental, and there is a limit of 1 HFCWO device per client, per lifetime.[24] The fee schedule, which was last updated in October 2020, lists the maximum allowable monthly rental fee for a HFCWO device (HCPCS E0483) as $1,224.07, and the maximum allowable fee for replacement parts (HCPCS A7025) as $465.90.[27]

Medicare

The local coverage determination for HFCWO devices (L33785) for Medicare, last updated in 2020, provides the following criteria for medical necessity[28]:

- There is a diagnosis of cystic fibrosis; or
- There is a diagnosis of bronchiectasis that has been confirmed by a high resolution, spiral, or standard CT scan and which is characterized by daily productive cough for at least 6 continuous months and frequent exacerbations requiring antibiotic therapy (2 or more times per year); chronic bronchitis and COPD in the absence of a confirmed diagnosis of bronchiectasis do not meet this criterion; or
- The beneficiary has one of the following neuromuscular disease diagnoses: post-polio; acid maltase deficiency; anterior horn cell diseases; multiple sclerosis; quadriplegia; hereditary muscular dystrophy; myotonic disorders; other myopathies; or paralysis of the diaphragm; and
- There must be well-documented failure of standard treatments to adequately mobilize retained secretions.
- It is not reasonable and necessary for a beneficiary to use both a HFCWO device and a mechanical in-exsufflation device.
- Replacement supplies, HCPCS A7025 and A7026, used with beneficiary owned equipment, are covered if the beneficiary meets the criteria listed above for the base device, HCPCS E0483. If these criteria are not met, the claim will be denied as not reasonable and necessary.

Private Payers

Aetna updated its policy for HFCWO devices in March 2021 and anticipates re-review in January 2022. This policy provides the following criteria for medical necessity[29]:

- Patient has a well-documented failure of standard treatments to adequately mobilize retained secretions; and
- Patient has been diagnosed with bronchiectasis confirmed by CT scan, characterized by daily productive cough for at least 6 continuous months or by frequent (i.e., more than 2 times per year) exacerbations requiring antibiotic therapy; or
- Patient has been diagnosed with cystic fibrosis or immotile cilia syndrome; or
- Patient has been diagnosed with 1 of the following neuromuscular diseases: acid maltase deficiency; anterior horn cell diseases, including amyotrophic lateral sclerosis; hereditary muscular dystrophy; multiple sclerosis; myotonic disorders; other myopathies; paralysis of the diaphragm; post-polio; or quadriplegia regardless of underlying etiology.
- Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy.

- Aetna considers continuous high-frequency chest wall oscillation therapy for the treatment of bronchitis, and secretion-induced atelectasis to be experimental and investigational because there is insufficient evidence of effectiveness.
- Aetna considers high-frequency chest compression systems experimental and investigational for other indications in members who do not meet medical necessity criteria above (e.g., alpha 1antitrypsin deficiency, cerebral palsy, childhood atelectasis, chronic inflammatory demyelinating polyneuropathy, coma, Cri-du-Chat syndrome, individuals with acute pneumonic respiratory failure receiving mechanical ventilation, interstitial lung disease, kyphosis, leukodystrophy, protein alveolar proteinosis, scoliosis, stiff-person (stiff-man) syndrome, and Zellweger syndrome; not an all-inclusive list) because their effectiveness for these indications has not been established.

Cigna updated its policy for HFCWO devices in March 2021 and anticipates reviewing this policy in September 2021. This policy provides the following criteria for medical necessity[30]:

- Patient has been diagnosed with cystic fibrosis and there is a failure, intolerance, or contraindication to home chest physiotherapy, or it cannot be provided; or
- Patient has been diagnosed with bronchiectasis confirmed by high-resolution computed tomography; has daily productive cough for at least 6 months or requires antibiotic treatment of exacerbations 2 or more times per year; and failure of standard treatments (e.g., pharmacotherapy, postural drainage, chest percussion, vibration) to mobilize secretions; or
- Patient has been diagnosed with neuromuscular disease; that disease is characterized by excessive mucus production, infection and difficulty clearing secretions; and there is a failure, intolerance, or contraindication to standard treatment (e.g., pharmacotherapy, postural drainage, daily chest percussion) and standard airway clearance device (e.g., mechanical percussors, positive expiratory pressure device).

Moda updated its policy for HFCWO devices in March 2021, and considers airway oscillating devices, mechanical percussors, positive expiration masks to be medically necessary to assist in mobilizing respiratory tract secretions for patients with cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome, or asthma. Their policy requires prior authorization and provides the following criteria for medical necessity[31]:

- Face-to-face visit with provider within 6 months prior to the request;
- Documentation of failure of standard treatments to adequately mobilize retained secretions;
- Cannot request both HFCWO and mechanical in-exsufflation device; and
- One or more of the following conditions are met:
    - A high resolution, spiral, or standard CT scan documentation of bronchiectasis that is characterized by 1 or more of the following: at least 6 months of daily productive cough, or frequent exacerbations requiring antibiotic therapy (i.e., more than 2 times per year);
    - The patient does not have chronic bronchitis and COPD in the absence of confirmed diagnosis of bronchiectasis
    - Cystic fibrosis or immotile cilia syndrome
    - The patient has one of the following neuromuscular diseases: acid maltase deficiency; anterior horn cell diseases, including amyotrophic lateral sclerosis; hereditary muscular dystrophy; multiple sclerosis; myotonic disorders; other myopathies; paralysis of the

diaphragm; post-polio; quadriplegia regardless of etiology; lung transplant recipients who are unable to tolerate standard chest physiotherapy, and who have submitted a request within the first 6 months post-operatively.

- Indications for which HFCWO is considered investigational include alpha 1-antitrypsin deficiency, childhood atelectasis, cerebral palsy, coma, kyphosis, leukodystrophy, scoliosis, and stiff-person syndrome.

Moda's policy specifically names the following devices but notes that the list is not all-inclusive: Frequencer, SmartVest, MedPulse Respiratory Vest System, The Vest Airway Clearance System, ABI Vest, Respin11 Bronchial Clearance System, and InCourage Vest/System.[31]

Regence BlueCross BlueShield updated their policy for oscillatory devices in July 2020 and anticipates starting a new review for their policy in June 2021. This policy required prior authorization and provides the following criteria for medical necessity for use of HFCWO devices[32]:

- Among patients with cystic fibrosis: demonstrated need for airway clearance and documentation that standard chest physiotherapy has failed, is not tolerated, or cannot be performed. Failure is defined as continued frequent severe exacerbations of respiratory distress.
- Among patients with chronic diffuse bronchiectasis: demonstrated need for airway clearance; documentation that standard chest physiotherapy has failed, is not tolerated, or cannot be performed; and high resolution or spiral chest tomography scan to document bronchiectasis, plus either daily productive cough for at least 6 continuous months, or exacerbations requiring antibiotic therapy 3 or more times per year.
- Among patients with COPD or conditions associated with other neuromuscular disorders, HFCWO devices are considered investigational.

Evidence-based Guidelines and Recommendations

National Institute for Health Care and Excellence (NICE)

The NICE guidelines published in 2017 for the diagnosis, treatment, and management of cystic fibrosis explicitly state that HFCWO devices should not be offered as an airway clearance technique for people with cystic fibrosis except in exceptional clinical circumstances.[33] There is a special cystic fibrosis team that decides when circumstances are exceptional; otherwise, the guidance states that based on published evidence, HFCWO is not as effective as other airway clearance techniques.[33]

We did not identify any NICE guidelines for the diagnosis, treatment, and management of bronchiectasis, COPD, or neuromuscular diseases that explicitly included HFCWO devices in the recommendations sections.

European Respiratory Society

The European Respiratory Society published guidelines in 2017 for the management of adult bronchiectasis from determinations made by a task force comprised of respiratory medicine, microbiology, physiotherapy, thoracic surgery, primary care, and patient advocates.[34] Systematic reviews of published evidence were conducted, reviewed, and debated by this task force during 4 in-person meetings that took place over 21 months, with additional communication by email and teleconference when drafting the final recommendations.[34] Any task force members with conflicts of interest were forced to abstain from all voting activities during the process of developing

recommendations.[34] The guideline recommends that patients with bronchiectasis be taught to use an airway clearance technique 1 to 2 times daily by a trained physiotherapist, as a weak recommendation based on low quality of evidence.[34] HFCWO therapy was one of multiple airway clearance techniques that the task force considered while making this recommendation, but there was no statement of which airway clearance technique might be superior to others.[34] There was a strong recommendation for use of pulmonary rehabilitation in patients with impaired exercise capacity.[34]

European Neuromuscular Centre (ENMC)

ENMC convened a meeting in March 2017 with 21 internationally recognized experts in airway clearance techniques for patients with neuromuscular disorders.[35] Several of the participating experts had received funding, honoraria, or expenses for travel paid for by manufacturers of devices that assist in airway clearance.[35] HFCWO devices were addressed in the review that the experts published after the meeting in the section related to peripheral airway clearance techniques, which also included discussion of intrapulmonary percussive ventilation, manual chest compression, and chest wall strapping.[35] Other sections of the review included information about manually assisted cough, assisted inspiration and expiration, mechanical insufflation-exsufflation.[35] The authors concluded that peripheral airway clearance techniques such as HFCWO therapy may be effective, and should be considered for use in management of chronic lung disease associated with neuromuscular disorders alongside manually assisted cough or other equipment to clear secretions from airways.[35] The authors noted that HFCWO devices are expensive in comparison to other available devices and techniques.[35]

American College of Chest Physicians

The American College of Chest Physicians published an expert panel report in 2018 on treating cough due to non–cystic fibrosis bronchiectasis and cystic fibrosis bronchiectasis with nonpharmacological airway clearance after conducting a systematic review of published evidence.[36] The authors were unable to make recommendations due to insufficient evidence, but provided the following consensus-based suggestions[36]:

- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that they be taught airway clearance techniques by professionals with advanced training in airway clearance techniques.
- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that the frequency of airway clearance should be determined by disease severity and amount of secretions.
- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that airway clearance techniques are individualized as there are many different techniques.

American Association for Respiratory Care (AARC)

AARC published clinical practice guidelines about the effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients with impaired secretion clearance, based on a systematic review of published studies.[37] The guidelines provided focused recommendations for adult and pediatric patients without cystic fibrosis; adult and pediatric patients with neuromuscular disease, respiratory muscle weakness, or impaired cough; and postoperative adult and pediatric patients.[37] These guidelines note that HFCWO was not recommended for adult and pediatric patients with neuromuscular disease,

respiratory muscle weakness, or impaired cough, due to insufficient evidence.[37] Airway clearance techniques were not recommended for routine treatment of COPD or post-operative care.[37] The authors propose the following process questions when considering the use of airway clearance techniques in these populations[37]:

- Does the patient have difficulty clearing airway secretions? Are retained secretions affecting gas exchange or lung mechanics? Focus on patient's level of difficulty for mobilizing and expectorating secretions.
- Which therapy is likely to provide the greatest benefit with the least harm?
- What is the cost of the therapy in terms of the device cost and clinician time to apply or supervise the therapy? The authors note that this is especially relevant for devices or therapies to be used at home.
- What factors are important to the patient about performing airway clearance therapy? This is an important consideration, given the lack of high-quality evidence that any one technique is more effective than other techniques.

Recommendations and Guidelines from Professional Societies

American Thoracic Society

The American Thoracic Society published a clinical practice guideline in 2011 for the diagnosis and management of stable COPD in partnership with the American College of Physician, American College of Chest Physicians, and European Respiratory Society.[38] This guideline did not consider oscillation devices as part of standard management of COPD.[38]

Recommendations from Advocacy Organizations

American Lung Association

The American Lung Association does not list HFCWO devices as part of the management and treatment of cystic fibrosis, bronchiectasis, or COPD.[39-41]

Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation promotes the use of clinical practice guidelines from a systematic review of the evidence that the foundation commissioned in 2009 to compare airway clearance techniques and devices.[42] The review concluded that airway clearance should be part of managing cystic fibrosis to maintain lung function and improve quality of life, and assessed that this could provide a moderate net benefit based on fair quality body of evidence.[43] No airway clearance technique or device was found to be superior to others, and the authors recommended that airway clearance technique be individualized to the patient in consideration of age, preference, and history of adverse events.[43]

References

1. Rogers DF, Barnes PJ. Treatment of airway mucus hypersecretion. *Ann Med.* 2006;38(2):116-125. doi: 10.1080/07853890600585795.
2. Centers for Disease Control and Prevention. Chronic obstructive pulmonary disease (COPD). 2021; https://www.cdc.gov/copd/index.html. Accessed May 3, 2021.
3. Centers for Disease Control and Prevention. Cystic fibrosis. 2021; https://www.cdc.gov/genomics/disease/cystic_fibrosis.htm. Accessed May 3, 2021.
4. Weycker D, Hansen GL, Seifer FD. Prevalence and incidence of noncystic fibrosis bronchiectasis among US adults in 2013. *Chron Respir Dis.* 2017;14(4):377-384. doi: 10.1177/1479972317709649.
5. Konstan M, Berger M. Current understanding of the inflammatory process in cystic fibrosis: onset and etiology. *Pediatr Pulmonol.* 1997;24(2):137-142.
6. Morrison L, Milroy S. Oscillating devices for airway clearance in people with cystic fibrosis. *The Cochrane database of systematic reviews.* 2020;4:CD006842. doi: https://dx.doi.org/10.1002/14651858.CD006842.pub5.
7. Dymedso. Frequencer. 2021; https://dymedso.com/frequencer/. Accessed April 21, 2021.
8. US Food and Drug Administration. Dymedso Frequencer V2 and Frequencer V2x airway clearance device. 2011; https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103176.pdf. Accessed April 22, 2021.
9. Electromed Inc. The smart shoice for HFCWO therapy. 2021; https://smartvest.com/smart-choice-for-hfcwo-therapy/?gclid=EAIaIQobChMIz92Cqb-K7gIV2zizAB01yAGgEAAYASAAEgJoaPD_BwE. Accessed April 21, 2021.
10. US Food and Drug Administration. Special 510(k) summary. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132794.pdf. Accessed April 22, 2021.
11. Hill-Rom Inc. The Vest airway clearance system, model 105. 2021. Accessed April 21, 2021.
12. US Food and Drug Administration. 510(k) summary of safety and effetiveness. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122480.pdf. Accessed April 22, 2021.
13. respInnovation. RespIn 11 bronical clearance system. 2021; http://respin11.com/index.php/respin/respin-11. Accessed April 21, 2021.
14. US Food and Drug Administration. Premarket notification 510(k). 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121170.pdf. Accessed April 22, 2021.
15. Philips, RespirTech. InCourage system airway clearance device. 2021; https://www.usa.philips.com/healthcare/product/HC500055/incourage-system-airway-clearance-device. Accessed April 22, 2021.
16. US Food and Drug Administration. 510(k) summary of safety and effectiveness. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf5/K051383.pdf. Accessed April 22, 2021.
17. International Biophysics Corportation. AffloVest mobile mechanial HFCWO vest therapy. 2020; https://www.afflovest.com/. Accessed Aprik 22, 2021.
18. Lee AL, Burge AT, Holland AE. Airway clearance techniques for bronchiectasis. *Cochrane Database Syst Revs.* 2015(11):CD008351. doi: 10.1002/14651858.CD008351.pub3.
19. Nicolini A, Grecchi B, Banfi P. Effectiveness of two high frequency chest wall oscillation techniques in patients with bronchiectasis: a randomized controlled preliminary study. *Panminerva Med.* 2020. doi: 10.23736/S0031-0808.20.03735-0.
20. Nicolini A, Grecchi B, Ferrari-Bravo M, Barlascini C. Safety and effectiveness of the high-frequency chest wall oscillation vs intrapulmonary percussive ventilation in patients with severe COPD. *International journal of chronic obstructive pulmonary disease.* 2018;13:617-625. doi: 10.2147/COPD.S145440.

21. Lange DJ, Lechtzin N, Davey C, et al. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. *Neurology.* 2006;67(6):991-997.
22. Clinical Trials Registry. Clinical effectiveness of high frequency chest wall oscillation (HFCWO) in a bronchiectasis population. 2021; https://clinicaltrials.gov/ct2/show/NCT04271969. Accessed April 23, 2021.
23. Nicolini A, Cardini F, Landucci N, Lanata S, Ferrari-Bravo M, Barlascini C. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. *BMC Pulm Med.* 2013;13:21. doi: 10.1186/1471-2466-13-21.
24. McIlwaine MP, Alarie N, Davidson GF, et al. Long-term multicentre randomised controlled study of high frequency chest wall oscillation versus positive expiratory pressure mask in cystic fibrosis. *Thorax.* 2013;68(8):746-751. doi: 10.1136/thoraxjnl-2012-202915.
25. Clinical Trials Registry. A pilot study to evaluate the use of the Vest system for treatment of bronchiectasis patients in the home setting. 2020; https://clinicaltrials.gov/ct2/show/NCT04017312. Accessed April 23, 2021.
26. Washington Apple Health (Medicaid). Respiratory care billing guide. 2019; https://www.hca.wa.gov/assets/billers-and-providers/Respiratory-care-bi-20190101.pdf.
27. Washington Health Care Authority. Provider billing guides and fee schedules. 2021; https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedules. Accessed April 30, 2021.
28. Centers for Medicare & Medicaid Services. Local coverage determination: high frequency chest wall oscillation devices (L33785). 2020; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33785. Accessed Arpil 22, 2021.
29. Aetna. Chest physiotheray and airway clearance devices. 2021; http://www.aetna.com/cpb/medical/data/1_99/0067.html. Accessed April 22, 2021.
30. Cigna. Airway clearance devices in the ambulatory setting. 2021; https://chk.static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_Future/mm_0069_coveragepositioncriteria_airway_clearance_devices.pdf. Accessed April 22, 2021.
31. Moda. High frequency chest wall oscillation devices (HFCWO). 2021; https://www.modahealth.com/pdfs/med_criteria/HighFrequencyChestWallOscillationDevices.pdf. Accessed April 22, 2021.
32. Regence BlueCross BlueShield. Oscillatory devices for the treatment of cystic fibrosis and other respiratory conditions. 2020; http://blue.regence.com/trgmedpol/dme/dme45.pdf. Accessed April 22, 2021.
33. National Institute for Health and Care Excellence. Cystic fibrosis: diagnosis and management NG78. 2017; https://www.nice.org.uk/guidance/ng78/chapter/Recommendations#pulmonary-monitoring-assessment-and-management. Accessed April 30, 2021.
34. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J.* 2017;50(3). doi: 10.1183/13993003.00629-2017.
35. Chatwin M, Toussaint M, Goncalves MR, et al. Airway clearance techniques in neuromuscular disorders: a state of the art review. *Respir Med.* 2018;136:98-110. doi: 10.1016/j.rmed.2018.01.012.
36. Hill AT, Barker AF, Bolser DC, et al. Treating cough due to non-CF and CF bronchiectasis with nonpharmacological airway clearance: CHEST expert panel report. *Chest.* 2018;153(4):986-993. doi: 10.1016/j.chest.2018.01.014.
37. Strickland SL, Rubin BK, Drescher GS, et al. AARC clinical practice guideline: effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. *Respir Care.* 2013;58(12):2187-2193. doi: 10.4187/respcare.02925.

38. Qaseem A, Wilt T, Weinberger S, et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med.* 2011;155:179-191. doi: 10.7326/0003-4819-155-3-201108020-00008.
39. American Lung Association. Treating COPD. 2021; https://www.lung.org/lung-health-diseases/lung-disease-lookup/copd/treating. Accessed April 30, 2021.
40. American Lung Association. Treating and managing bronchiectasis. 2021; https://www.lung.org/lung-health-diseases/lung-disease-lookup/bronchiectasis/treating-and-managing. Accessed April 30, 2021.
41. American Lung Association. Treating and managing cystic fibrosis. 2021; https://www.lung.org/lung-health-diseases/lung-disease-lookup/cystic-fibrosis/treating-and-managing. Accessed April 30, 2021.
42. O'Conner M, O'Sullivan B, Cystic Fibrosis Foundation. Cystic fibrosis airway clearance therapies clinical care guidelines. 2019; https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/CF-Airway-Clearance-Therapies-Clinical-Care-Guidelines/. Accessed April 19, 2021.
43. Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respir Care. 2009;54(4):522-537.
44. Yuan N, Kane P, Shelton K, Matel J, Becker BC, Moss RB. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. *J Child Neurol*. 2010;25(7):815-821. doi: https://dx.doi.org/10.1177/0883073809350223.

Suggested citation: Godlewski B, Durbin S, King VJ, & Smits A, Walker E, Gingerich J. *Coverage guidance: high-frequency chest wall oscillation devices*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University; 2022.

Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

Appendix B. GRADE Evidence Profile

Certainty Assessment (Confidence in Estimate of Effect) for Cystic Fibrosis							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
1	RCT	Serious	Not serious	Serious	Serious	Small samples, short follow-up	Very low ●○○○
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
3	RCTs	Serious	Not serious	Serious	Serious	Small samples, short follow-up	Very low ●○○○
Exercise Capacity							
0							
Breathlessness or Cough							
0							

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for Bronchiectasis							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
1	RCT	Serious	Unable to rate (single study)	Not serious	Serious		Very low ●○○○
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Serious	Unable to rate (single study)	Not serious	Serious		Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for COPD							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
0							
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Moderate	Unable to rate (single study)	Serious	Serious	Short intervention period and follow-up	Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for Pulmonary Complications from Neuromuscular Disease Resulting in Chronic Lung Disease							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
0							
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Serious	Unable to rate (single study)	Serious	Serious	Small sample, short follow-up	Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Appendix C. Methods

Scope Statement

Populations

Children and adults with cystic fibrosis, bronchiectasis, chronic obstructive pulmonary disorder, or pulmonary complications from neuromuscular disease resulting in chronic lung disease

Population scoping notes: Patients without any of the above conditions are excluded.

Interventions

High-frequency chest wall oscillation devices approved for use in the US

Intervention exclusions: None

Comparators

Home physiotherapy, mechanical percussors, positive expiratory pressure masks, airway clearance devices (e.g., oscillating devices, intrapulmonary percussive ventilation), or other types of high-frequency chest wall oscillation devices not approved for use in the US

Outcomes

Critical: Hospitalizations, mortality

Important: Frequency of pulmonary exacerbations requiring antibiotics, changes in exercise capacity, symptoms of breathlessness or cough

Considered but not selected for GRADE Table: Sputum volume or weight, forced expiratory volume, forced vital capacity, total lung capacity

Key Questions

KQ1: What is the comparative effectiveness of high-frequency chest wall oscillation devices?

KQ2: Does the comparative effectiveness of high-frequency chest wall oscillation devices vary by:

a. Disease type

b. Patient characteristics

c. Device characteristics

KQ3: What are the harms of high-frequency chest wall oscillation devices?

KQ4: What is the comparative cost effectiveness of high-frequency chest wall oscillation devices?

Contextual Questions

CQ1: What resources are required to use the interventions and comparators?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2015.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

An Ovid MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms *chest wall oscillation, high frequency chest wall oscillation, high frequency Chest wall compression, Frequencer, SmartVest, MedPulse Respiratory Vest, Vest Airway Clearance System, ABI Vest, Respin11, bronchial clearance, InCourage Vest,* and *Afflovest*. The search was limited to publications in English published since 2015. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the identified systematic reviews for cystic fibrosis and bronchiectasis. An additional search for randomized controlled trials published since 2006 was conducted for chronic obstructive pulmonary disorder and neuromuscular diseases with pulmonary complications leading to chronic lung disease, because no systematic reviews were identified for these populations. The searches were limited to publications in English.

Searches for clinical practice guidelines were limited to those published since 2015. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

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
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussive ventilation system and related accessories
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
CPT	
94669	Mechanical chest wall oscillation to facilitate lung function, per session
ICD-10-CM	
B91	Sequelae of poliomyelitis
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
E84	Cystic fibrosis
G12	Spinal muscular atrophy and related syndromes
G14	Post-polio syndrome
G35	Multiple sclerosis
G71.0-G71.1	Primary disorders of muscles
G72	Other and unspecified myopathies
G73.7	Myopathy in diseases classified elsewhere
G82.5	Quadriplegia
G95	Syringomyelia and syringobulbia
J44	Chronic obstructive pulmonary disease
J47	Bronchiectasis
J98.6	Disorders of diaphragm
M33	Dermatopolymyositis
M34.82	Systemic sclerosis with myopathy
M35.03	Sicca syndrome with myopathy
Q33.4	Congenital bronchiectasis

Note. Inclusion on this list does not guarantee coverage.