# Airway Clearance Devices (for New Mexico Only)

**Policy Number**: CS054NM.D
**Effective Date**: March 1, 2026

➲ Instructions for Use

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**Related Policy**

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for New Mexico Only)

## Application

This Medical Policy only applies to the state of New Mexico.

## Coverage Rationale

**A 2-month rental trial of a high-frequency chest wall oscillation (HFCWO) system is proven and medically necessary in the management of neuromuscular diseases, Bronchiectasis, and cystic fibrosis when criteria have been met.**

**HFCWO is unproven and not medically necessary for any other condition due to insufficient evidence of efficacy.** For additional medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Airway or Secretion Clearance Devices (Custom) – UHG.

Click here to view the InterQual® criteria.

For all indications for a HFCWO system, an initial 2-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For medical necessity determination to address ongoing use, refer to the InterQual® criteria.

**Combination continuous positive expiratory pressure, continuous high-frequency oscillation, and nebulized medication therapy devices for oscillation and lung expansion are considered unproven and not medically necessary.**

**Intrapulmonary percussive ventilation devices for home use are considered unproven and not medically necessary.**

## Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

## Definitions

Refer to the federal, state, or contractual definitions that supersede the definitions below.

**Bronchiectasis**: A chronic respiratory disease with multiple causes that is associated with different medical conditions. Clinical symptoms include the dilation (ectasia) of the airways or bronchi, with primary clinical manifestations of recurrent, chronic, or refractory infections. Clinically significant Bronchiectasis will have at least two of the following: a cough most days of the week, sputum production most days of the week, a history of exacerbations. The presence of Bronchiectasis is confirmed and classified radiographically, by high resolution, spiral, or standard computed tomography scan (Aliberti et al., 2022).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description |
|---|---|
| A7021 | Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter) |
| A7025 | High frequency chest wall oscillation system vest, replacement for use with patient- owned equipment, each |
| A7026 | High frequency chest wall oscillation system hose, replacement for use with patient- owned equipment, each |
| E0469 | Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device |
| E0481 | Intrapulmonary percussive ventilation system and related accessories |
| E0483 | High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each |

| Diagnosis Code | Description |
|---|---|
| A80.0 | Acute paralytic poliomyelitis, vaccine-associated |
| A80.1 | Acute paralytic poliomyelitis, wild virus, imported |
| A80.2 | Acute paralytic poliomyelitis, wild virus, indigenous |
| A80.30 | Acute paralytic poliomyelitis, unspecified |
| A80.39 | Other acute paralytic poliomyelitis |
| A80.4 | Acute nonparalytic poliomyelitis |
| A80.9 | Acute poliomyelitis, unspecified |
| B91 | Sequelae of poliomyelitis |
| E74.02 | Pompe disease |
| E74.4 | Disorders of pyruvate metabolism and gluconeogenesis |
| E84.0 | Cystic fibrosis with pulmonary manifestations |
| E84.9 | Cystic fibrosis, unspecified |
| G12.0 | Infantile spinal muscular atrophy, type I [Werdnig-Hoffman] |
| G12.1 | Other inherited spinal muscular atrophy |
| G12.21 | Amyotrophic lateral sclerosis |

| Diagnosis Code | Description |
|---|---|
| G12.22 | Progressive bulbar palsy |
| G12.25 | Progressive spinal muscle atrophy |
| G12.8 | Other spinal muscular atrophies and related syndromes |
| G12.9 | Spinal muscular atrophy, unspecified |
| G14 | Post-polio syndrome |
| G35.A | Relapsing-remitting multiple sclerosis |
| G35.B0 | Primary progressive multiple sclerosis, unspecified |
| G35.B1 | Active primary progressive multiple sclerosis |
| G35.B2 | Non-active primary progressive multiple sclerosis |
| G35.C0 | Secondary progressive multiple sclerosis, unspecified |
| G35.C1 | Active secondary progressive multiple sclerosis |
| G35.C2 | Non-active secondary progressive multiple sclerosis |
| G35.D | Multiple sclerosis, unspecified |
| G71.00 | Muscular dystrophy, unspecified |
| G71.036 | Limb girdle muscular dystrophy due to fukutin related protein dysfunction |
| G71.11 | Myotonic muscular dystrophy |
| G71.20 | Congenital myopathy, unspecified |
| G71.21 | Nemaline myopathy |
| G71.220 | X-linked myotubular myopathy |
| G71.228 | Other centronuclear myopathy |
| G71.29 | Other congenital myopathy |
| G71.3 | Mitochondrial myopathy, not elsewhere classified |
| G71.8 | Other primary disorders of muscles |
| G72.41 | Inclusion body myositis [IBM] |
| G72.89 | Other specified myopathies |
| G73.1 | Lambert-Eaton syndrome in neoplastic disease |
| G73.3 | Myasthenic syndromes in other diseases classified elsewhere |
| G73.7 | Myopathy in diseases classified elsewhere |
| G80.0 | Spastic quadriplegic cerebral palsy |
| G82.50 | Quadriplegia, unspecified |
| G82.51 | Quadriplegia, C1-C4 complete |
| G82.52 | Quadriplegia, C1-C4 incomplete |
| G82.53 | Quadriplegia, C5-C7 complete |
| G82.54 | Quadriplegia, C5-C7 incomplete |
| J47.0 | Bronchiectasis with acute lower respiratory infection |
| J47.1 | Bronchiectasis with (acute) exacerbation |
| J47.9 | Bronchiectasis, uncomplicated |
| J98.6 | Disorders of diaphragm |
| M33.02 | Juvenile dermatomyositis with myopathy |
| M33.12 | Other dermatomyositis with myopathy |
| M33.22 | Polymyositis with myopathy |
| M33.92 | Dermatopolymyositis, unspecified with myopathy |
| M34.82 | Systemic sclerosis with myopathy |
| M35.03 | Sicca syndrome with myopathy |
| Q33.4 | Congenital bronchiectasis |

| Diagnosis Code | Description |
|---|---|
| R53.2 | Functional quadriplegia |
| Z99.11 | Dependence on respirator [ventilator] status |

# Description of Services

In healthy individuals, clearance of secretions from the respiratory tract is accomplished primarily through ciliary action. Increased production of airway secretions is usually cleared by coughing. However, a number of conditions, including asthma, chronic obstructive pulmonary disease, cystic fibrosis, mucociliary disorders, neuromuscular disease, and metabolic disorders can result in inadequate airway clearance, either because of increased volume of secretions, increased viscosity of secretions, or difficulty coughing. These secretions accumulate in the bronchial tree, occluding small passages and interfering with adequate gas exchange in the lungs. They also serve as a culture medium for pathogens, leading to a higher risk for chronic infection and deterioration of lung function. The blockage of mucus can result in Bronchiectasis, which is the abnormal stretching and enlarging of the respiratory passages. Bronchiectasis may complicate chronic bronchitis, one of the groups of respiratory illnesses referred to as chronic obstructive pulmonary disease, and it can occur as a complication of cystic fibrosis.

When coughing alone cannot adequately clear secretions, other therapies are used. Conventional chest physical therapy has been shown to result in improved respiratory function and has traditionally been accomplished using percussion and postural drainage. Postural drainage and percussion are usually taught to family members so that the therapy may be continued at home when needed in chronic disease. This highly labor-intensive activity requires the daily intervention of a trained caregiver, which may lead to poor adherence to the recommended treatment plan.

To improve adherence and allow individuals to independently manage their disease, high-frequency chest wall compression/high-frequency chest wall oscillation devices have been developed to improve mucociliary clearance and lung function. High-frequency chest wall compression is a mechanical form of chest physical therapy that consists of an inflatable vest connected by tubes to a small air-pulse generator. The air-pulse generator rapidly inflates and deflates the vest, compressing and releasing the chest wall up to 20 times per second. The vibratory forces of these devices are thought to lower mucus viscosity.

Intrapulmonary percussive ventilation is a mechanized form of chest physical therapy that delivers mini bursts (more than 200 per minute) of respiratory gases to the lungs via a mouthpiece. Its purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The individual controls variables such as inspiratory time, delivery rates, and peak pressure. Alternatively, a therapist will do a slapping or clapping of the individual's chest wall.

# Clinical Evidence

## High-Frequency Chest Wall Oscillation System for Neuromuscular Disease

Sheers et al. (2024) reviewed the respiratory management strategies for individuals with neuromuscular disease, with a focus on the efficacy of mechanical insufflation-exsufflation (MI-E) therapy. The authors emphasized the need for further evaluation of MI-E to ensure its effectiveness in clinical practice. Hyperinflation therapies were identified as beneficial for cough augmentation and could potentially improve thoracic range of motion. The review advocates for a personalized approach to treatment, tailored to each individual's specific needs. For individuals with neuromuscular disease who are experiencing recurrent respiratory exacerbations despite optimal proximal airway clearance techniques (ACTs), the authors recommended initiating a peripheral airway clearance regimen and assessing for chronic suppurative lung disease. While peripheral ACTs may offer benefit, evidence that supports the use of mucolytics is lacking in this population.

Khirani et al. (2024) conducted a national prospective survey to review the prescription of ACT and lung volume recruitment (LVR) devices for home use in children in France. All centers of the French national pediatric noninvasive ventilation (NIV) network (28 pediatric university hospitals distributed among 24 cities) were invited to complete an anonymous questionnaire for every child aged ≤ 20 years who started a treatment with an ACT/LVR device between 2022 and 2023. The devices comprised MI-E, intermittent positive pressure breathing (IPPB), intrapulmonary percussive ventilation (IPV), and/or invasive mechanical ventilation/NIV for ACT/LVR. Overall, 139 participants were included from 13 centers. IPPB was started in 83 participants (60%), MI-E in 43 (31%), and IPV in 30 (22%). No participants used invasive mechanical ventilation/NIV for ACT/LVR. The devices were prescribed mainly by pediatric pulmonologists [103 (74%)]. The mean age at initiation was 8.9 ±5.6 (0.4-18.5) years. The ACT/LVR devices were prescribed mainly in participants with neuromuscular disorders [n = 66 (47%)] and neurodisability [n = 37 (27%)]. The main initiation criteria were cough

assistance (81%) and airway clearance (60%) for MI-E, thoracic mobilization (63%) and vital capacity (47%) for IPPB, and airway clearance (73%) and repeated respiratory exacerbations (57%) for IPV. The parents were the main carers who were performing the treatment at home. The authors concluded that IPPB was the most prescribed technique, followed by MI-E and IPV. The age, diseases, and initiation criteria were extremely heterogeneous, which makes it difficult to draw recommendations based on the French practice of these techniques. ACT/LVR devices may be successfully used in young children and children with neurodisability, even in cases of poor cooperation. This study has several limitations. First, the number of participants was small, and all the participants were not included in the study due to logistical problems in some centers. Second, the diseases in the participants who were initiated on ACT/LVR may have varied according to the centers due to the local recruitment of participants, with a center effect in some cases. The authors did not analyze the center effect on the type of ACT/LVR device prescribed according to the initiation criteria and/or pathology, as the number of participants per center was too small. Therefore, this study did not discuss the best indications and settings for the different devices. Fourth, this study analyzed only the initial prescription, without information on the real objective use of ACT/LVR, as many devices do not have adherence reports. Finally, the immediate effects of ACT/LVR and their long-term impact on the number of respiratory infections/exacerbations or hospitalizations were not reported. In addition, the authors did not gather the secretion burden and qualitative benefit with ACT/LVR devices. Prospective studies are required to validate the indications, best timing, and settings of the different ACT/LVR devices in children according to their diseases and to assess their efficacy.

Huang et al. (2022) conducted a systematic review and meta-analysis to evaluate the efficacy of high-frequency chest wall oscillation (HFCWO) for sputum expectoration and hospital length of stay in individuals with acute exacerbations of chronic obstructive pulmonary disease (AECOPD). The improvements in pulmonary function and oxygenation were also investigated. This systematic review and meta-analysis followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Automated literature database searches were conducted from the earliest records to March 31, 2022. The methodological quality of the included studies was assessed using the Cochrane Risk of Bias tool (RoB 2.0), and meta-analysis software (RevMan 5.4) was used to analyze the data. From 5,439 identified articles, 13 studies (with 756 individuals) were included in this meta-analysis. Compared with other ACTs, HFCWO increased expectorated sputum volume by 6.18 mL (95% CI, 1.71-10.64; $I^2$ = 87%) and shortened the hospital stay by 4.37 days (95% CI, -7.70 to -1.05; $I^2$ = 84%). However, forced expiratory volume in 1 second ($FEV_1$; %), $PaO_2$, and $PaCO_2$ did not improve significantly. The authors concluded that individuals with AECOPD may benefit from HFCWO therapy. HFCWO enables individuals with AECOPD to excrete more sputum and shorten their hospital stays. However, due to heterogeneity among the research included, these results should be interpreted with caution. This study has limitations that should be considered that may diminish the evidence for the findings. First, this meta-analysis excluded outpatient studies and only included studies that evaluated the effect of AECOPD on key outcomes (e.g., sputum expectoration, hospital stay). In this meta-analysis, the HFCWO intervention components varied across studies, as did the session durations and frequencies of the oscillations, potentially resulting in study heterogeneity. In addition, this study includes both English and Chinese literature; however, some of the Chinese literature is unfamiliar outside of China, which may limit the generalizability of the study. The findings of this study need to be validated by well-designed studies.

González-Bellido et al. (2021) conducted a randomized controlled trial (RCT) to investigate the use and safety of high-frequency chest wall compression (HFCWC) for nonhospitalized infants with acute viral bronchiolitis (AVB). The aim of the present study was to evaluate the immediate effects and safety of HFCWC compared with those of ACTs in children with AVB. In this RCT in nonhospitalized infants (aged 0-12 months old) with mild to moderate AVB, children were randomized into two groups: ACTs (20 minutes of prolonged slow expiration and provoked cough) or HFCWC (15 min). A single session was performed, and children were evaluated at baseline and at 10 minutes and 20 minutes after the treatments. Outcome measures were the Wang Severity Score, $SpO_2$, sputum wet weight, and the presence of adverse events. A total of 91 infant participants, with a mean age of 7.9 ±2.6 months, were included. Noteworthy between-group differences were found in the Wang Score, which was 0.28 points lower in the ACTs group. There was a greater increase of infants who were classified as normal and a greater decrease of those classified as mild, according to the Wang Score, when ACTs were used compared with the use of HFCWC. The sputum wet weight was lower in participants who were treated with the ACTs ($p < 0.001$). Although $SpO_2$ improved in both groups, no differences were found between them. There was also no difference in adverse events, and many children did not present any adverse events after 20 minutes. The authors concluded that the use of HFCWC induced similar clinical effects as ACTs and was safe for nonhospitalized infants with AVB. Both techniques reduced respiratory symptoms and acutely improved $SpO_2$. This study has some limitations. First, only the immediate effects were evaluated, which does not allow the authors to extrapolate results for continuing daily therapy use. Second, the study had no control group (salbutamol and hypertonic saline only) to compare with the ACTs and HFCWC groups. Further investigation is needed before the clinical usefulness of this procedure is proven.

Barto et al. (2020) conducted a retrospective study to evaluate hospitalization patterns before and after initiation of HFCWO therapy as well as antibiotic use and self-reported metrics of quality of life in adult patients with non–cystic fibrosis bronchiectasis. Data from 2,596 patients from a registry of adult patients with bronchiectasis using HFCWO

therapy were used. Self-reported outcomes were also reviewed by cross-checking with sampled patient charts and were found to be consistent. The number of patients who had at least one respiratory-related hospitalization decreased from 49.1% (192/391) in the year before to 24.0% (94/391) in the year after starting HFCWO therapy (p value < 0.001). At the same time, the number of patients who required three or more hospitalizations dropped from 14.3% (56/391) to 5.6% (22/391). Patients who were currently taking oral antibiotics for respiratory conditions decreased from 57.7% on initiation of therapy to 29.9% within 1 year (p < 0.001). Patients who subjectively rated their "overall respiratory health" as good to excellent increased from 13.6% on initiation of therapy to 60.5% in 1 year (p < 0.001), and those who rated their "ability to clear your lungs" as good to excellent increased from 13.9% to 76.6% (p < 0.001). The authors concluded that patients with non–cystic fibrosis bronchiectasis had improved self-reported outcomes associated with the initiation of HFCWO therapy, as measured by number of hospitalizations, antibiotic use, and the subjective experience of airway clearance. The improvement was observed early on after initiation of therapy and sustained for at least 1 year. This study has limitations. This was a nonrandomized study design without a control group. Further research, with well-designed RCTs, is needed to validate these findings.

Leemans et al. (2020) conducted an RCT aimed at assessing the effectiveness of a newly developed mobile ACT device [mHFCWO (The Monarch Airway Clearance System)] in participants with cystic fibrosis. A standard nonmobile HFCWO device (sHFCWO) was used as a comparator. This was a randomized, open-label, crossover pilot study. Participants with cystic fibrosis were treated with each device. Sputum was collected during and after each therapy session, while spirometry tests, Brody score assessment, and functional respiratory imaging were performed before and after treatments. Wet weight of sputum that was collected during and after treatment was similar for mHFCWO and sHFCWO (6.53 ±8.55 vs 5.80 ±5.82; p = 0.777). The mHFCWO treatment led to a decrease in specific airway volume (9.55 ±9.96 vs 8.74 ±9.70 mL/L; p < 0.001) while increasing specific airway resistance (0.10 ±0.16 vs 0.16 ±0.23 KPA*S; p < 0.001). These changes were heterogeneously distributed throughout the lung tissue and were greater in the distal areas, suggesting a shift of mucus. Changes were accompanied by an overall improvement in the Brody Index (57.71 ±16.55 vs 55.20 ±16.98; p = 0.001). The authors concluded that the newly developed mobile device provides airway clearance for individuals with cystic fibrosis that is comparable to that with a nonmobile sHFCWO device, yielding a change in airway geometry and patency by the shift of mucus from the more peripheral regions to the central airways. Limitations to this study include the small sample size. In addition, the intensity of both HFCWO devices required some adjustment, depending on the participant's individual needs, and variation in the settings could have some effect on results in a small study. Further investigation is needed before the clinical usefulness of this device is proven.

In a 2019 Custom Product Brief on The Vest® Airway Clearance System, ECRI identified and reviewed one international single-blinded RCT (n = 73), one international open-label RCT (n = 50), and one prospective case series (n = 25) conducted in the US. They stated that the available evidence is too limited in quantity and quality to permit conclusions on the product's safety and effectiveness for use in hospitalized individuals with respiratory failure who do not have cystic fibrosis. While all reported short-term positive outcomes, individuals' prognoses and complication risks were not directly comparable. The case series was at a high risk of bias from the lack of a control group. The two RCTs included appropriate control groups and treatment randomization but were at a high risk of bias because of the small sample size and single-center focus; additionally, one study lacked blinding as to treatment group. Each study was conducted in a different country, and results may not generalize to other health systems. Larger, multicenter, blinded RCTs are needed to validate how well HFCWO with the Vest System works relative to other mechanical or intrapulmonary flow percussion devices to guide health care provider decisions.

McIlwaine et al. (2019) conducted a meta-analysis to determine the effectiveness and acceptability of positive expiratory pressure (PEP) devices compared with those of other forms of physiotherapy as a means of improving mucus clearance and other outcomes in people with cystic fibrosis. A search from 1982 to 2017 was performed of RCTs in which PEP was compared with any other form of physiotherapy in people with cystic fibrosis. This included postural drainage and percussion (PDPV), active cycle of breathing techniques (ACBT), oscillating PEP (O-PEP) devices, thoracic oscillating devices, bilevel positive airway pressure, and exercise. A total of 28 studies (involving 788 children and adults) were included in the review; 18 studies, involving 296 individuals, were crossover in design. Data were not published in sufficient detail in most of these studies to perform any meta-analysis. In 22 of the 28 studies, the PEP technique was performed using a mask; in three of the studies, a mouthpiece was used with nose clips; and in three studies, it was unclear whether a mask or mouthpiece was used. These studies compared PEP with ACBT, autogenic drainage, oral O-PEP devices, HFCWO, bilevel positive airway pressure, and exercise. $FEV_1$ was the review's primary outcome and the most frequently reported outcome in the studies (24 studies; 716 individuals). Single interventions or series of treatments that continued for up to 3 months demonstrated little or no difference in effect between PEP and other methods of airway clearance on this outcome (low- to moderate-quality evidence). However, long-term studies had equivocal or conflicting results regarding the effect on this outcome (low- to moderate-quality evidence). A second primary outcome was the number of respiratory exacerbations. There was a lower exacerbation rate in individuals who were using PEP compared with other techniques when used with a mask for at least 1 year (five studies; 232 individuals; moderate- to high-quality

evidence). In one of the included studies, which used PEP with a mouthpiece, it was reported (personal communication) that there was no difference in the number of respiratory exacerbations (66 individuals; low-quality evidence). Individuals' preferences were reported in 10 studies, and in all studies with an intervention period of at least 1 month, this was in favor of PEP. The results for the remaining outcome measures (including a third primary outcome of mucus clearance) were not examined or reported in sufficient detail to provide any high-quality evidence; only very low- to moderate-quality evidence was available for other outcomes. There was limited evidence that was reported on adverse events; these were measured in five studies, two of which found no events. In a study in which infants who were receiving either PEP or PDPV experienced some gastroesophageal reflux, this was more severe in the PDPV group (26 infants; low-quality evidence). In PEP vs O-PEP, adverse events were only reported in the flutter group (five individuals reported dizziness, which improved after further instructions on device use was provided) (22 individuals; low-quality evidence). In PEP vs HFCWO, from one long-term high-quality study (107 individuals), there was little or no difference in terms of number of adverse events; however, those in the PEP group had fewer adverse events related to the lower airways than HFCWO (high-certainty evidence). Many studies had a risk of bias, as they did not report how the randomization sequence was either generated or concealed. Most studies reported the number of dropouts and reported on all planned outcome measures. The authors concluded that the evidence that was provided by this review is of variable quality but suggested that all techniques and devices described may have a place in the clinical treatment of people with cystic fibrosis. Following meta-analyses of the effects of PEP vs those of other ACTs on lung function and individuals' preferences, this Cochrane Review demonstrated that there was high-quality evidence that showed a reduction in pulmonary exacerbations when PEP using a mask was used compared with HFCWO. Exacerbation rate and time to first exacerbation in longer-term trials (at least 12 months) between compared ACTs may be of greater use and relevance in cystic fibrosis, which is a long-term disease.

Auger et al. (2017) conducted a systematic review to analyze 12 studies that examined the benefit and risk ratio for the use of MI-E devices for airway clearance in individuals with neuromuscular diseases. The inclusion criteria for outcomes were survival outcome, hospitalization rate, respiratory exacerbation outcome, pulmonary function parameters, adverse events, and quality of life. The studies selected included four RCTs, three comparative studies, and five observational studies. The authors were unable to validate the use of MI-E devices for cough augmentation in individuals with neuromuscular diseases, as there is a lack of robust scientific evidence. Further research is necessary to ensure the best treatment for individuals with neuromuscular diseases.

In a cohort study that compared health care claims before and after initiation of HFCWO, Lechtzin et al. (2016) examined whether this modality leads to improved respiratory outcomes, as measured by lower health care use in individuals who have a chronic neuromuscular disease. Data were obtained from two large databases of commercial insurance claims. Individuals who were included in the study (n = 426, pediatric and adult) were commercial insurance members with an International Classification of Diseases, Ninth Revision, code for a neuromuscular disease and a claim for HFCWO between 2007 and 2011. To account for the possibilities of misclassification based on diagnoses and bias due to loss to follow-up, outcomes between those lost to follow-up and those who were not were compared, and similar results were found. The authors concluded that total medical costs, hospitalizations, and pneumonia claims were less after (vs before) initiation of HFCWO in a broad group of individuals with neuromuscular disease. Subject to the limitations that administrative data did not capture how HFCWO was used and that HFCWO may be a marker of generally better care, the authors' findings lend support to the routine use of this intervention in the care of individuals with neuromuscular disease. These findings are limited by the lack of a concurrent comparison group that was undergoing a different therapeutic approach.

Lee et al. (2015) conducted a systematic review and meta-analysis to determine the effects of ACTs on rates of acute exacerbation, incidence of hospitalization, and health-related quality of life (HRQOL) in individuals with acute and stable bronchiectasis. The secondary objective was to determine whether ACTs are safe for individuals with acute and stable bronchiectasis and if ACTs have beneficial effects on physiology and symptoms in individuals with acute and stable bronchiectasis. The Cochrane Airways Group Specialized Register of Trials from inception to November 2015 and PEDro in March 2015 were searched, and relevant journals were hand searched. Randomized controlled parallel and crossover trials that compared an ACT vs no treatment, sham ACT, or directed coughing in individuals with bronchiectasis were included in this review. Seven studies, involving 105 individuals, met the inclusion criteria of this review, six of which were crossover in design. Six studies included adults with stable bronchiectasis; the other study examined clinically stable children with bronchiectasis. Three studies provided single treatment sessions, two lasted 15 to 21 days, and two were longer-term studies. The interventions varied; some control groups received a sham intervention, and others were inactive. The methodological quality of these studies was variable, with most studies failing to use concealed allocation for group assignment and with absence of blinding of individuals and personnel for outcome measure assessment. Heterogeneity between studies precluded inclusion of these data in the meta-analysis; therefore, the review is narrative. One study, including 20 adults, that compared an airway oscillatory device vs no treatment found no difference in the number of exacerbations at 12 weeks (low-quality evidence). Data were not available for assessment of the impact of ACTs on time to exacerbation, duration or incidence of hospitalization, or total number of hospitalized days. The same

study reported clinical improvements in HRQOL on both disease-specific and cough-related measures. The median difference in the change in total St. George's Respiratory Questionnaire score over 3 months in this study was 7.5 units [p value = 0.005 (Wilcoxon)]. Treatment that consisted of HFCWO or a mix of ACTs prescribed for 15 days improved HRQOL compared with no treatment (low-quality evidence). Two studies reported mean increases in sputum expectoration with airway oscillatory devices in the short term of 8.4 mL (95% CI, 3.4-13.4 mL) and in the long term of 3 mL (p value = 0.02). HFCWO improved $FEV_1$ by 156 mL and forced vital capacity (FVC) by 229.1 mL when applied for 15 days, but other types of ACTs showed no effect on dynamic lung volumes. Two studies reported a reduction in pulmonary hyperinflation among adults with non-PEP ACTs [difference in functional residual capacity of 19%, p value < 0.05; difference in total lung capacity (TLC) of 703 mL, p value = 0.02] and with airway oscillatory devices (difference in functional residual capacity of 30%, p value < 0.05) compared with no ACTs. Low-quality evidence suggests that ACTs (HFCWO, airway oscillatory devices, or a mix of ACTs) reduce symptoms of breathlessness and cough and improve ease of sputum expectoration compared with no treatment (p value < 0.05). ACTs had no effect on gas exchange, and no studies reported the effects of antibiotic usage. Among studies that explored airway oscillating devices, investigators reported no adverse events. The authors concluded that ACTs appear to be safe for individuals (adults and children) with stable bronchiectasis and may account for improvements in sputum expectoration, selected measures of lung function, symptoms, and HRQOL. The role of these techniques in acute exacerbation of bronchiectasis is unknown. In view of the chronic nature of bronchiectasis, additional data are needed to establish the short-term and long-term clinical value of ACTs for patient-important outcomes and for long-term clinical parameters that impact disease progression in individuals with stable bronchiectasis, allowing further guidance on the prescription of specific ACTs for people with bronchiectasis.

In a single-center, investigator-initiated, prospective study in 22 participants, Fitzgerald et al. (2014) assessed the clinical feasibility of HFCWC therapy in neurologically impaired children with respiratory symptoms. Participants were studied for 12 months before and 12 months after initiation of HFCWC therapy, and 15 participants were followed up for an additional 12 months. The threshold of adherence to the therapy was 70%. The number of pulmonary exacerbations that required hospitalization was recorded, noting that 45% of the participants required hospital admission before initiation of HFCWC therapy. This rate decreased to 36% after the first year and to 13% after the second year with this therapy. There was a statistically significant reduction in the number of hospital days at follow-up compared with prior to treatment. Use of an assisted-cough device or the presence of tracheostomy did not significantly affect hospitalization days. The authors concluded that regular HFCWC therapy may reduce the number of hospitalizations in neurologically impaired children. These findings are limited by the lack of a concurrent comparison group that was undergoing a different therapeutic approach.

Nicolini et al. (2013) conducted an RCT to evaluate the effectiveness of treatment with HFCWO in participants with bronchiectasis. The aim of this study was to find the more efficacious treatment in participants with bronchiectasis: traditional techniques of chest physiotherapy (CPT) vs high-frequency oscillation of the chest wall in participants with bronchiectasis. A total of 37 participants were enrolled. Seven of them were excluded. Computer randomization divided the participants into three groups: 10 participants treated with HFCWO by using the Vest Airway Clearance System, 10 participants treated with traditional techniques of airway clearance (PEP bottle, PEP mask, slow expiration with glottis opened in lateral position, or vibratory PEP), and 10 participants who received medical therapy only (control group). To be eligible for enrollment, participants had to be between 18 and 85 years old and have a diagnosis of bronchiectasis, confirmed on high-resolution computed tomography. Exclusion criteria included the lack of informed consent, signs of exacerbation, and cystic fibrosis. Before the treatment, each participant had blood tests, sputum volume and cell count, pulmonary function tests, and on the quality-of-life inventories [Modified Medical Research Council (MMRC), COPD Assessment Test (CAT), and Breathlessness, Cough, and Sputum Scale (BCSS)]. The results were processed through the covariance analysis, performed with the R-Project statistical program. It has been considered a positive result p < 005. Both treatments (traditional CPT and HFCWO) showed improvement in some biochemical and functional respiratory tests as well as in quality of life compared with the control group. The use of HFCWO compared with CPT also produced improvement in blood inflammation parameter C-reactive protein ($p \leq 0.019$), parameters of lung functionality associated with bronchial obstruction (FVC and $FEV_1$; $p \leq 0.006$ and $p \leq 0.001$), and dyspnea. Improvement in quality-of-life scales was noted (BCSS and CAT; both $p \leq 0.001$). No changes in total cell count in sputum samples were observed in the two groups. In the HFCWO group, a reduction of neutrophils percentage ($p \leq 0.002$) was noted as well as an increase of macrophages percentage ($p \leq 0.012$). The authors concluded that the HFCWO technique provides an improvement both in pulmonary function and quality-of-life–related parameters in individuals with chronic hypersecretive disease. Since those individuals need daily airway clearance, this treatment should be included among the principal options in CPT. This study has limitations. The amount of daily sputum volume was not reported. In addition, the short-term follow-up did not allow for assessment of intermediate- and long-term outcomes. Further investigation is needed before the clinical usefulness of this procedure is proven.

## Combination Continuous Positive Expiratory Pressure, Continuous High Frequency Oscillation, and Nebulized Medication Therapy Devices for Oscillation and Lung Expansion

Due to insufficient quality evidence or consistency of findings, combination continuous PEP, continuous high-frequency oscillation, and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary.

Main and Rand (2023) conducted a systematic review and meta-analysis to evaluate the effectiveness (in terms of respiratory function, respiratory exacerbations, and exercise capacity) and acceptability (in terms of individual preference, adherence, and quality of life) of conventional CPT (CCPT) for people with cystic fibrosis compared with alternative ACTs. The authors included randomized or quasirandomized controlled trials (including crossover design) that lasted at least 7 days and compared CCPT with alternative ACTs in people with cystic fibrosis. The primary outcomes were (1) pulmonary function tests and (2) number of respiratory exacerbations per year. The secondary outcomes were (1) quality of life, (2) adherence to therapy, (3) cost-benefit analysis, (4) objective change in exercise capacity, (5) additional lung function tests, (6) ventilation scanning, (7) blood oxygen levels, (8) nutritional status, (9) mortality, (10) mucus transport rate, and (11) mucus wet or dry weight. Outcomes were reported as short term (7-20 days), medium term (more than 20 days to up to 1 year), and long term (over 1 year). A total of 21 (778 individuals) studies comprising seven short-term, eight medium-term, and six long-term studies were included. Studies were conducted in the US (10), Canada (five), Australia (two), the UK (two), Denmark (one), and Italy (one), with a median of 23 individuals per study (range, 13-166 individuals). Individuals' ages ranged from newborns to 45 years; most studies only recruited children and young people. Sixteen studies reported the sex of individuals (375 male; 296 female). Most studies compared modifications of CCPT with a single comparator, but two studies compared three interventions, and another compared four interventions. The interventions varied in the duration of treatments, times per day, and periods of comparison, making meta-analysis challenging. All evidence was very low certainty. Overall, 19 studies reported the primary outcomes of $FEV_1$ and FVC and found no difference in change from baseline in $FEV_1$ percent predicted or rate of decline between groups for either measure. Most studies suggested equivalence between CCPT and alternative ACTs, including PEP, extrapulmonary mechanical percussion, ACBT, O-PEP devices, autogenic drainage, and exercise. Where single studies suggested superiority of one ACT, these findings were not corroborated in similar studies; pooled data generally concluded that the effects of CCPT were comparable to those of alternative ACTs. Regarding CCPT vs PEP, the authors are uncertain whether CCPT improves lung function or has an impact on the number of respiratory exacerbations per year compared with PEP (both very low-certainty evidence). There were no analyzable data for secondary outcomes, but many studies provided favorable narrative reports on the independence achieved with PEP mask therapy. Regarding CCPT vs extrapulmonary mechanical percussion, the authors are uncertain whether CCPT improves lung function compared with extrapulmonary mechanical percussions (very low-certainty evidence). The annual rate of decline in average forced expiratory flow between 25% and 75% of FVC ($FEF_{25-75}$) was greater with high-frequency chest compression than CCPT in medium- to long-term studies, but there was no difference in any other outcome. Regarding CCPT vs ACBT, the authors are uncertain whether CCPT improves lung function compared with ACBT (very low-certainty evidence). The annual decline in $FEF_{25-75}$ was worse in individuals who were using the forced expiration technique component of ACBT only [mean difference (MD), 6.00; 95% CI, 0.55-11.45; one study, 63 individuals; very low-certainty evidence]. One short-term study reported that directed coughing was as effective as CCPT for all lung function outcomes but with no analyzable data. One study found no difference in hospital admissions and days in hospital for exacerbations. Regarding CCPT vs O-PEP, the authors are uncertain whether CCPT improves lung function compared with O-PEP devices (Flutter device and IPV); however, only one study provided analyzable data (very low-certainty evidence). No study reported data for the number of exacerbations. There was no difference in results for the number of days in hospital for an exacerbation, number of hospital admissions, and number of days of intravenous antibiotics; this was also true for other secondary outcomes. Regarding CCPT vs autogenic drainage, the authors are uncertain whether CCPT improves lung function compared with autogenic drainage (very low-certainty evidence). No studies reported the number of exacerbations per year; however, one study reported more hospital admissions for exacerbations in the CCPT group (MD, 0.24; 95% CI, 0.06-0.42; 33 individuals). One study provided a narrative report of a preference for autogenic drainage. Regarding CCPT vs exercise, the authors are uncertain whether CCPT improves lung function compared with exercise (very low-certainty evidence). An analysis of original data from one study demonstrated a higher $FEV_1$ percent predicted (MD, 7.05; 95% CI, 3.15-10.95; p = 0.0004), FVC (MD, 7.83; 95% CI, 2.48-13.18; p = 0.004), and $FEF_{25-75}$ (MD, 7.05; 95% CI, 3.15-10.95; p = 0.0004) in the CCPT group; however, the study reported no difference between groups (likely because the original analysis accounted for baseline differences). The authors concluded that they are uncertain whether CCPT has a more positive impact on respiratory function, respiratory exacerbations, individual preference, adherence, quality of life, exercise capacity, and other outcomes compared with alternative ACTs, as the certainty of the evidence is very low. There was no advantage in respiratory function of CCPT over alternative ACTs, but this may reflect insufficient evidence rather than real equivalence. Narrative reports indicated that individuals prefer self-administered ACTs. This review is limited by a paucity of well-designed, adequately powered, long-term studies. This review cannot yet recommend any

single ACT above others; physiotherapists and people with cystic fibrosis may wish to try different ACTs until they find an ACT that suits them best.

Morrison and Milroy (2020) conducted a systematic review and meta-analysis to identify whether oscillatory devices, oral or chest wall, are effective for mucociliary clearance and whether they are equivalent or superior to other forms of airway clearance in the successful management of secretions in people with cystic fibrosis. Search criteria included RCTs and controlled clinical studies of oscillating devices compared with any other form of physiotherapy in people with cystic fibrosis. Single-treatment interventions (therapy technique used only once in the comparison) were excluded. Two authors independently applied the inclusion criteria to publications, assessed the quality of the included studies, and assessed the evidence using GRADE (Grading of Recommendations Assessment, Development, and Evaluation). The searches identified 82 studies (330 references); 39 studies (total of 1,114 individuals) met the inclusion criteria. Studies varied in duration from up to 1 week to 1 year; 20 of the studies were crossover in design. The studies also varied in type of intervention and the outcomes measured; data were not published in sufficient detail in most of these studies, so meta-analysis was limited. Few studies were considered to have a low risk of bias in any domain. It is not possible to blind individuals and clinicians to physiotherapy interventions, but 13 studies did blind the outcome assessors. The quality of the evidence across all comparisons ranged from low to very low. $FEV_1$ was the most frequently measured outcome, and while many of the studies reported an improvement in those people using a vibrating device compared with before the study, there were few differences when comparing the different devices to each other or to other ACTs. One study identified an increase in frequency of exacerbations requiring antibiotics while using HFCWO compared with PEP (low-quality evidence). There were some small but significant changes in secondary outcome variables such as sputum volume or weight but not wholly in favor of oscillating devices, and due to the low- or very low-quality evidence, it is not clear whether these were due to the particular intervention. Individuals' satisfaction was reported in 13 studies but again with low- or very low-quality evidence and not consistently in favor of an oscillating device, as some individuals preferred breathing techniques or techniques used prior to the study interventions. The results for the remaining outcome measures were not examined or reported in sufficient detail to provide any high-level evidence. The authors concluded that there was no clear evidence that oscillation was a more or less effective intervention overall than other forms of physiotherapy; furthermore, there was no evidence that one device was superior to another. The findings from one study that showed an increase in the frequency of exacerbations requiring antibiotics while using an oscillating device compared with PEP may have significant resource implications. More adequately powered, long-term RCTs are necessary, and the outcomes measured should include frequency of exacerbations, individual preference, adherence to therapy, and general satisfaction with treatment. Increased adherence to therapy may then lead to improvements in other parameters, such as exercise tolerance and respiratory function. Additional evidence is needed to evaluate whether oscillating devices combined with other forms of airway clearance are efficacious in people with cystic fibrosis. There may also be a requirement to consider the cost implication of devices over other forms of equally advantageous ACTs. Using the GRADE method to assess the quality of the evidence, we judged this to be low or very low quality, which suggests that further research is very likely to have an impact on confidence in any estimate of effect that is generated by future interventions.

Huynh et al. (2019) conducted a multicenter, nonrandomized, prospective study to examine the impact of OLE therapy using continuous high-frequency oscillation and continuous PEP on postoperative pulmonary complications (PPCs) in high-risk participants. In stage I, Current Procedural Terminology and International Classification of Diseases codes were queried for participants (n = 210) who were undergoing thoracic, upper abdominal, or aortic open procedures at three institutions from December 2014 to April 2016. Participants were selected randomly. Age, comorbidities, American Society of Anesthesiologists Physical Status Classification scores, and PPC rates were determined. In stage II, 209 participants were enrolled prospectively from October 2016 to July 2017 using the same criteria. Stage II participants received OLE treatment and standard respiratory care. The PPCs rate [prolonged ventilation, high-level respiratory support, pneumonia, and intensive care unit (ICU) readmission] was compared. The authors also compared ICU length of stay, hospital length of stay, and mortality using t tests and analysis of covariance. Data are mean ±SD. There were 419 participants. Stage II participants were older (61.1 ±13.7 years vs 57.4 ±15.5 years; $p < 0.05$) and had higher American Society of Anesthesiologists scores. Treatment with OLE decreased PPCs from 22.9% (stage I) to 15.8% (stage II) ($p < 0.01$ adjusted for age, American Society of Anesthesiologists score, and operation time). Similarly, OLE treatment reduced ventilator time (23.7 ±107.5 hours to 8.5 ±27.5 hours; $p < 0.05$) and hospital length of stay (8.4 ±7.9 days to 6.8 ±5.0 days; $p < 0.05$). No differences in ICU length of stay, pneumonia, or mortality were observed. The authors concluded that aggressive treatment with OLE reduces PPCs and resource use in high-risk surgical individuals. Well-designed, adequately powered, prospective, controlled clinical trials in combination OLE treatment are needed to further describe safety and clinical efficacy.

## Intrapulmonary Percussive Ventilation

There is insufficient quality evidence or consistency of findings to support the long-term home use of IPV devices.

In an RCT, Hassan et al. (2024) evaluated the effectiveness of IPV in nonventilated, critically ill participants, focusing on ICU length of stay, oxygenation, and pulmonary complications. A total of 106 participants with respiratory impairment were randomly assigned to either the IPV or conventional physiotherapy group, with both groups receiving two treatment sessions daily. Data from 100 participants were analyzed for outcomes, including ICU length of stay, changes in oxygenation, respiratory rate, and radiological findings. The results showed that the median ICU length of stay was significantly shorter in the IPV group (3.5 days; IQR, 1.9-5.9 days) than the conventional physiotherapy group (5.2 days; IQR, 3.4-9.9 days), with an MD of 1.56 days (95% CI, 1.2-2.1 days; $p = 0.002$). IPV also led to a modest improvement in peripheral oxygen saturation (MD, 0.94%; 95% CI, 0.43%-1.45%; $p < 0.001$) and a reduction in respiratory rate (MD, 2.1 breaths/min; 95% CI, 0.9-3.2 breaths/min; $p < 0.001$). No significant difference was observed in radiological atelectasis scores ($p = 0.65$). The authors concluded that IPV may improve clinical outcomes in critically ill individuals with respiratory impairment by reducing ICU length of stay and respiratory rate, with a small benefit in oxygenation compared with conventional physiotherapy. However, limitations of the study included the single-center design, limited generalizability, and interruptions due to the COVID-19 pandemic, which delayed study completion.

Hassan et al. (2024) conducted a scoping review to assess the clinical application of IPV and identify potential inconsistencies in practice due to limited clinical guidance. The review aimed to summarize the methods and dosages of IPV that were used by clinicians and researchers to support more standardized application. Of 514 studies screened, 25 met the inclusion criteria. The findings revealed variability in both the clinical application and prescribed dosages of IPV. Despite this, common trends were identified and synthesized to assist clinicians in implementing IPV interventions more effectively. The authors noted limitations, including the potential omission of relevant studies and incomplete evidence in included studies, which hindered the development of a comprehensive clinical guideline due to heterogeneity. Nonetheless, they concluded that the summarized IPV application and dosage practices may serve as a useful reference for clinicians and contribute to the future development of standardized clinical practice guidelines.

Hassan et al. (2021b) conducted a retrospective pilot study to evaluate the safety and feasibility of IPV intervention in nonintubated patients who were admitted to an ICU. The medical records of 35 patients were reviewed, including 22 patients who received IPV intervention and 13 patients who were matched for age, sex, and primary diagnosis and received CPT. The records were audited for feasibility, safety, changes in oxygen saturation, chest x-ray changes, and ICU length of stay. A total of 104 treatment sessions (IPV 65 and CPT 39) were delivered to patients who were admitted with a range of respiratory conditions in critical care. Patients completed 97% of IPV sessions. No major adverse events were reported with IPV intervention. ICU length of stay in the IPV group was 9.6 ±6 days, and in the CPT group, it was 11 ±9 days ($p = 0.59$). Peripheral oxygen saturation before to post intervention was 92% ±4 to 96% ±4 in the IPV group and 95% ±4 to 95% ±3 in the CPT group. The authors concluded that application of the IPV intervention was feasible and safe in spontaneously breathing, nonintubated adult patients in critical care. The study is limited by its retrospective observations. There is a need for an adequately powered RCT to further evaluate the effects of IPV intervention in a nonintubated population in critical care.

Hassan et al. (2021a) performed a systematic review to summarize the evidence of the effectiveness of IPV on ICU length of stay and respiratory outcomes in critically ill individuals. A systematic search of IPV in ICUs was performed on five databases from 1979 to 2021. Studies were considered for inclusion if they evaluated the effectiveness of IPV in individuals aged ≥ 16 years who were receiving invasive or noninvasive ventilation or were breathing spontaneously in critical care or high-dependency units. Study titles and abstracts were screened, followed by data extraction by a full-text review. Due to a small number of studies and observed heterogeneities in the study methodology and population of individuals, a meta-analysis could not be included in this review. Of 306 identified abstracts, seven studies (630 individuals) met the eligibility criteria. Results of the included studies provide weak evidence to support the effectiveness of IPV in reducing ICU length of stay, improving gas exchange, and reducing respiratory rate. The authors concluded that based on the findings of this review, the evidence to support the role of IPV in reducing ICU length of stay, improving gas exchange, and reducing respiratory rate is weak. The therapeutic value of IPV in airway clearance, preventing pneumonia, and treating pulmonary atelectasis requires further investigation. This study has several limitations. The number of studies retrieved was small (seven). Heterogeneities that resulted from differences in study design, population of individuals, dosage, and frequency of IPV intervention were frequently observed in the included studies. Further, small sample sizes and poor methodological quality introduced some bias and weakened the strength of conclusions of this review. Further investigation is needed before the clinical usefulness of this procedure is proven.

Nicolini et al. (2018) conducted a 4-week RCT to determine if adding IPV or HFCWO with the best pharmacological therapy (PT) will provide clinical benefit to individuals with COPD over just CPT. There was a total of 63 participants who were randomized into three groups (20 participants completed the trial in each group): IPV group (treated with PT and IPV), PT group with (treated with PT and HFCWO), and control group (treated with PT alone). The primary outcomes that were measured were the Dyspnea Scale (MMRC) and BCSS, along with daily life activity (CAT). The secondary outcomes that were measured were pulmonary function testing, arterial blood gas analysis, and hematologic

examinations. Participants in both the IPV and HFCWO group had marked improvement in dyspnea and MMRC, the BCSS, and the CAT compared with the control group. IPV participants had an improvement in BCSS ($p = 0.001$) and CAT ($p = 0.02$) scores compared with HFCWO participants. Both IPV and HFCWO secondary outcomes improved compared with the control group. In the group comparison analysis of the IPV group and HFCWO group variables, there was marked improvement in the IPV group in TLC and TLC% ($p = 0.03$); residual volume (RV) and RV% ($p = 0.04$); and diffusing lung capacity monoxide, maximal inspiratory pressure, and maximal lung capacity ($p = 0.01$). The authors concluded that (1) both IPV and HFCWO can improve lung function, muscular strength, dyspnea, and overall health status and (2) IPV demonstrated better effectiveness in improving test results in small bronchial airways and alveolar ventilation (RV and diffusing lung capacity monoxide) and muscular strength (maximal inspiratory pressure and maximal lung capacity) as well as scores on daily life activity and health status assessment scales (BCSS and CAT) than HFCWO. A multicenter, larger population study, with measurement of primary and secondary outcomes over a longer term, is needed. Limitations of this study include the single-center design, small sample size, and short duration as well as a lack of masking or a sham procedure. Furthermore, the intervention was delivered by a physical therapist; therefore, these findings may not be generalizable to IPV used at home and without professional supervision or for conditions other than COPD.

Reychler et al. (2018) conducted a systematic review to summarize the physiological and clinical effects that are related to the use of IPV as an ACT in chronic obstructive airway diseases. Using predetermined criteria, a search was conducted in the PubMed, PEDro, and Scopus online databases. The outcomes of interest included immediate or prolonged physiological effects (e.g., gas exchange, cardiorespiratory parameters, lung function, mechanics) and clinical effects (e.g., symptoms, adverse effects, length of hospital stay). A total of 109 studies were identified, and after further evaluation, 12 studies were included in the review. Of those, one study evaluated individuals with bronchiectasis (n = 22), four studies evaluated individuals with cystic fibrosis (n = 78), and six studies (one study included phase 1 and 2 results) evaluated individuals with COPD (n = 178). In individuals with COPD, IPV improved gas exchange during exacerbation and reduced the hospital length of stay; however, IPV was no more beneficial than other ACTs when individuals were stable. Two studies reported complications or discomfort with IPV, and in another study, two individuals did not tolerate settings with a higher frequency of percussions (1.220 cm $H_2O$-350 c/min and 1.840 cm $H_2O$-350 c/min). In individuals with cystic fibrosis, cardiorespiratory parameters and lung function did not improve with IPV. One study reported mild hemoptysis, which was associated with a respiratory infection. In individuals with bronchiectasis, dyspnea and respiratory frequency improved after one session of IPV; however, there was no difference in sputum dry weight. In individuals with productive bronchiectasis, the immediate efficacy of IPV vs that of other ACTs did not differ. Minor adverse events (dry throat, nausea, and/or fatigue) were reported in 27% of individuals who were treated with both IPV and chest physical therapy. The authors concluded that the use of IPV as an ACT in chronic obstructive airway diseases is not supported by sufficiently strong evidence to recommend routine use in this population of individuals.

## *Clinical Practice Guidelines*

### American Academy of Neurology (AAN)

An AAN practice parameter states that there is insufficient data to support or refute HFCWC for clearing airway secretions in patients with amyotrophic lateral sclerosis (Miller et al., 2009).

### American College of Chest Physicians (ACCP)

Hill et al. (2018) conducted a systematic review on airway clearance in bronchiectasis due to cystic fibrosis and other causes by using nonpharmacological methods, as recommended by international guidelines, to develop recommendations or suggestions to update the 2006 CHEST guideline on cough. The systematic search for evidence examined the following question: "Is there evidence of clinically important treatment effects for non-pharmacological therapies in cough treatment for patients with bronchiectasis?". The populations selected were all patients with bronchiectasis due to cystic fibrosis or non–cystic fibrosis bronchiectasis. The interventions that were explored were the nonpharmacological airway clearance therapies. The comparison populations included those who were receiving standard therapy and/or placebo. Clinically important outcomes that were explored were exacerbation rates, quality of life, hospitalizations, and mortality. In both cystic fibrosis and non–cystic fibrosis bronchiectasis, there were systematic reviews and overviews of systematic reviews that were identified. Despite these findings, there were no large RCTs that explored the impact of airway clearance on exacerbation rates, quality of life, hospitalizations, or mortality. The authors concluded that there is insufficient evidence that any ACT is consistently more effective than any other for clinically important outcomes in cystic fibrosis bronchiectasis.

### American Thoracic Society (ATS)

In a consensus statement on the respiratory care of patients with Duchenne muscular dystrophy (DMD), the ATS states that effective airway clearance is critical for patients with DMD to prevent atelectasis and pneumonia. Ineffective airway clearance can hasten the onset of respiratory failure and death, whereas early intervention to improve airway clearance can prevent hospitalization and reduce the incidence of pneumonia. HFCWC has been used in patients with

neuromuscular weakness, but there are no published data on which to base a recommendation. Any airway clearance device that is predicated on normal cough is less likely to be effective in patients with DMD without concurrent use of assisted cough. Patients with DMD should be taught strategies to improve airway clearance and how to use those techniques early and aggressively.

The ATS makes the following recommendations:

- Use assisted cough technologies in patients whose clinical history suggests difficulty in airway clearance or whose PCF is less than 270 L/minute and/or whose maximal expiratory pressures are less than 60 cm $H_2O$.
- The committee strongly supports the use of MI-E in patients with DMD and recommends further studies of this modality.
- Home pulse oximetry is useful to monitor the effectiveness of airway clearance during respiratory illnesses and to identify patients with DMD who need hospitalization.

(Finder et al., 2004)

## British Thoracic Society

In 2012, the British Thoracic Society created guidelines for respiratory management of children with neuromuscular weakness. The guideline summarizes the available evidence in this field and provides recommendations that will aid health care professionals in delivering good-quality patient care.

The summary of recommendations for identifying children at risk of respiratory complications is listed as follows:

- Clinical assessment of respiratory health should be part of every medical consultation for children with neuromuscular weakness and should be directed toward identifying progressive muscle weakness, ability to cope with respiratory infection, aspiration, progression of scoliosis, and sleep-disordered breathing.
- Ulna length or arm span should be used to predict lung function in children with neuromuscular disease whose height cannot be accurately measured.
- Vital capacity should be measured in all patients with neuromuscular disease who are capable of performing spirometry as part of the respiratory assessment.
- Cough peak flow should be used as part of the assessment of effective secretion clearance in children with neuromuscular disease over the age of 12 years.
- Assessment for sleep-disordered breathing should be carried out no less than annually for children with neuromuscular disease who have a vital capacity of < 60% predicted and for children who have become nonambulant because of progressive muscle weakness or who never attain the ability to walk.
- Assessment for sleep-disordered breathing should be carried out no less than annually for all infants with weakness, children with neuromuscular weakness who have symptoms of obstructive sleep apnea or hypoventilation, children with clinically apparent diaphragmatic weakness, and children with rigid spine syndromes.
- In young children whose rate of disease progression is uncertain or in older children who have shown clinical deterioration, have had repeated infections, or develop symptoms of sleep-disordered breathing, sleep assessment may need to be more frequent than once a year.
- All children with abnormal overnight oximetry should undergo more detailed sleep monitoring with at least oxycapnography.
- When there is doubt about the cause of sleep-disordered breathing, overnight polysomnography or sleep polygraphy should be performed. Portable overnight oxycapnography or polygraphy in the home may be the most appropriate option for some patients.
- Children with neuromuscular disease with a history of swallowing difficulties should have a feeding assessment by a speech and language therapist, including a video fluoroscopy swallow assessment if the swallow is thought to be unsafe.

(Hull et al., 2012)

## National Institute for Health and Care Excellence (NICE)

In a 2018 MedTech innovation briefing, the NICE found no published guidelines on airway clearance in people with complex neurological needs.

In 2017, NICE published guidelines for cystic fibrosis diagnosis and management. The guideline recommendations regarding ACTs are as follows:

- Discuss the use of ACTs with people with cystic fibrosis, who do not have clinical evidence of lung disease, and their parents or carers (as appropriate). Provide them with training in ACTs and explain when to use them.
- Offer training in ACTs to people with cystic fibrosis, who have clinical evidence of lung disease, and their parents or carers (as appropriate).

- When choosing an ACT for people with cystic fibrosis:
  - Assess their ability to clear mucus from their lungs and offer an individualized plan to optimize this.
  - Take account of their preferences and (if appropriate) those of their parents and carers.
  - Take account of any factors that may influence adherence.
- Regularly assess the effectiveness of ACTs and modify the technique or use a different one, if needed.
- Do not offer HFCWO as an ACT for people with cystic fibrosis, except in exceptional clinical circumstances. The specialist cystic fibrosis team will decide whether these circumstances apply, and their decision would then be subject to the NHS England policy on Individual Funding Requests. Be aware that the evidence shows that HFCWO is not as effective as other ACTs.
- Consider using NIV in people with cystic fibrosis who have moderate or severe lung disease and cannot clear their lungs using standard ACTs.

# U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

## High-Frequency Chest Wall Compression Devices

High-frequency chest wall compression devices are designed to promote airway clearance and improve bronchial drainage. They are indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport. Refer to the following website for more information (use product code BYI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 14, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 03/01/2026 | **Coverage Rationale**<br>• Updated language pertaining to medical necessity clinical coverage criteria for a **high-frequency chest wall oscillation (HFCWO) system**; replaced reference to the "InterQual® Client Defined, CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) - UHG" with "InterQual® Client Defined, CP: Durable Medical Equipment, *Airway or* Secretion Clearance Devices (Custom) - UHG"<br>**Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service |

| Date | Summary of Changes |
|---|---|
| | ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested<br>○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services<br>○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures<br>○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information<br>• Archived previous policy version CS054NM.C |

# Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.