Airway Clearance Devices

Policy Number: DME 019.41
Effective Date: March 1, 2025

➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements

Coverage Rationale

➲ Refer to Benefit Considerations

A two-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, Secretion Clearance Devices (Custom) - UHG.

Click here to view the InterQual® criteria.

For all indications for a high-frequency chest wall oscillation system, an initial two-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 (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary.

Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not medically necessary.

Medical Records Documentation Used for Review

Benefit coverage for health services is determined by the member specific benefit plan document 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 service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

Definitions

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 (CT) scan. (Alberti, 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 the member specific benefit plan document 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
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	Multiple sclerosis

Diagnosis Code	Description
G71.00	Muscular dystrophy, unspecified
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
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 (COPD), cystic fibrosis (CF), mucociliary disorders, neuromuscular disease (NMD), and metabolic disorders can result in inadequate airway clearance, either because of increased volume of secretions, increased viscosity of secretions, or difficulty in 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, the abnormal stretching and enlarging of the respiratory passages. Bronchiectasis may complicate chronic bronchitis, one of the groups of respiratory illnesses referred to as COPD and it can occur as a complication of CF.

When coughing alone cannot adequately clear secretions, other therapies are used. Conventional chest physical therapy (CPT) has been shown to result in improved respiratory function and has traditionally been accomplished through the use

of 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 compliance with the recommended treatment plan.

To improve compliance and allow patients to independently manage their disease, HFCWC/high-frequency chest wall oscillation (HFCWO) devices have been developed to improve mucociliary clearance and lung function. HFCWC is a mechanical form of CPT 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.

An IPV is a mechanized form of chest physical therapy, which 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 patient controls variables such as inspiratory time, delivery rates and peak pressure. Alternatively, a therapist will do a slapping or clapping of the patient's chest wall.

Benefit Considerations

Some of the disorders for which high frequency chest wall compression is unproven are serious, rare diseases. Benefit coverage for an otherwise unproven service for the treatment of serious, rare diseases may occur when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions in these circumstances. Before using this policy, check the member specific benefit plan document and any federal or state mandates, if applicable.

Clinical Evidence

High-Frequency Chest Wall Oscillation System (HFCWOS) for Neuromuscular Disease

Khirani et al. (2024) conducted a national prospective survey to review the prescription of airway clearance technique and lung volume recruitment (ACT/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 fill in 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 mechanical in-exsufflation (MI-E), intermittent positive pressure breathing (IPPB), intrapulmonary percussive ventilation (IPV), and/or invasive mechanical ventilation (IMV)/NIV for ACT/LVR. One hundred and thirty-nine patients were included by 13 centers. IPPB was started in 83 (60%) patients, MI-E in 43 (31%) and IPV in 30 (22%). No patient used IMV/NIV for ACT/LVR. The devices were prescribed mainly by pediatric pulmonologists (103, 74%). Mean age at initiation was 8.9 ±5.6 (0.4-18.5) years old. The ACT/LVR devices were prescribed mainly in patients with neuromuscular disorders (n = 66, 47%) and neuro disability (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 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 the initiation criteria are 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 neuro disability, even in case of poor cooperation. This study has several limitations. First, the number of patients is small, and all the patients were not included in the study due to logistical problems in some centers. Second, the diseases of the patients who were initiated on ACT/LVR may vary according to the centers due to the local recruitment of patients, 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 patients 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 or 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 benefice of 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 patients 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 Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) 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 5439 identified articles, 13 studies (with 756 patients) were included in this meta-analysis. Compared to other airway clearance techniques, HFCWO increased expectorated sputum volume by 6.18 mL (95% CI: 1.71 to 10.64; I2 = 87%), shortened hospital stay by 4.37 days (95% CI: −7.70 to −1.05; I2 = 84%). However, FEV1 (%), PaO2, and PaCO2 did not improve significantly. The authors concluded AECOPD patients may benefit from HFCWO therapy. HFCWO enables AECOPD patients to excrete more sputum and shorten their hospital stays. However, due to heterogeneity among the included research, 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 and 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 compress (HFCWC) for non-hospitalized infants with acute viral bronchiolitis (AVB). The aim of the present study was to evaluate the immediate effects and safety of HFCWC as compared to airway clearance techniques in children with AVB. In this RCT in non-hospitalized infants (0–12 months old) with mild to moderate AVB, children were randomized into 2 groups: airway clearance techniques (20 min 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 min and 20 min after treatments. Outcomes measures were the Wang severity score, SpO2, sputum wet-weight, and the presence of adverse events. A total of 91 infant subjects, mean age 7.9 6 2.6 months, were included. Noteworthy between-group differences were found in the Wang score, which was 0.28 points lower in the airway clearance techniques group. There was a greater increase of infants classified as normal and a greater decrease of those classified as mild according to the Wang score when airway clearance techniques were used compared to the use of HFCWC. The sputum wet weight was lower in subjects treated with the airway clearance techniques ($p < .001$). AlthoughSpO2 improved in both groups, no differences were found between them. There was also no difference for adverse events, and the majority of children did not present any adverse events after 20 min. The authors concluded that the use of HFCWC induced similar clinical effects as airway clearance techniques and was safe for non-hospitalized infants with AVB. Both techniques reduced respiratory symptoms and acutely improved SpO2. 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 has no control group (salbutamol and hypertonic saline only) to compare to airway clearance techniques and HFCWC groups. Further investigation is needed before clinical usefulness of this procedure is proven.

Barto et al. (2020) conducted a retrospective study to evaluate hospitalization patterns before and after initiation of high frequency chest wall oscillation (HFCWO) therapy, as well as antibiotic use and self-reported metrics of quality of life in adult patients with non-cystic fibrosis bronchiectasis (NCFB). Data from 2596 patients from a registry of adult bronchiectasis patients using HFCWO therapy was used. Self-reported outcomes were also reviewed by cross-checking with sampled patient charts and 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 currently taking oral antibiotics for respiratory conditions decreased from 57.7% upon initiation of therapy to 29.9% within 1year ($p < 0.001$). Patients who subjectively rated their “overall respiratory health” as good to excellent increased from 13.6% upon initiation of therapy to 60.5% in 1year ($p < 0.001$) 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 NCFB patients showed 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 non-randomized study design without a control group. Further research with randomized controlled trials is needed to validate these findings.

Leemans et al. (2020) conducted a randomized controlled trial (RCT) aimed to assess the effectiveness of a newly developed mobile airway clearance technique (ACT) device (mHFCWO-The Monarch Airway Clearance System) in patients with cystic fibrosis (CF). A standard nonmobile HFCWO device (sHFCWO) was used as a comparator. This was a randomized, open-label, crossover pilot study. CF patients 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 collected during and after treatment was similar for mHFCWO and sHFCWO (6.53 ±8.55 vs 5.80 ±5.82; $p = .777$). The mHFCWO treatment led to a decrease in specific airway volume (9.55 ±9.96 vs 8.74 ±9.70 mL/L; $p < .001$), while increasing specific airway resistance (0.10 ±0.16 vs 0.16

±0.23 KPA*S; p < .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 = .001). The authors concluded that the newly developed mobile device provides airway clearance for CF patients comparable to 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 patient's individual needs and that variation in settings could have some effect on results in a small study. Further investigation is needed before clinical usefulness of this device is proven.

In a 2019 custom product brief on The Vest Airway Clearance System, ECRI identified and reviewed 1 international single-blind randomized controlled trial (RCT, n = 73), 1 international open label RCT (n = 50), and 1 prospective case series (n = 25) conducted in the U.S. 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 patients with respiratory failure who do not have CF. While all reported short-term positive outcomes, patient prognoses and complication risks weren't directly comparable. The case series was at high risk of bias from lack of a control group. The two RCTs included appropriate control groups and treatment randomization but were at high risk of bias because of small sample size, single-center focus, and 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 healthcare provider decisions.

McIlwaine et al. (2019) conducted a meta-analysis to determine the effectiveness and acceptability of positive expiratory pressure (PEP) devices compared to other forms of physiotherapy as a means of improving mucus clearance and other outcomes in people with cystic fibrosis (CF). A search from 1982 to 2017 was performed of randomized controlled studies in which PEP was compared with any other form of physiotherapy in people with CF. This included, postural drainage and percussion (PDPV), active cycle of breathing techniques (ACBT), oscillating PEP devices, thoracic oscillating devices, bilevel positive airway pressure (BiPaP) and exercise. A total of 28 studies (involving 788 children and adults) were included in the review; 18 studies involving 296 participants were cross-over 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 to ACBT, autogenic drainage (AD), oral oscillating PEP devices, high-frequency chest wall oscillation (HFCWO) and BiPaP and exercise. Forced expiratory volume in one second was the review's primary outcome and the most frequently reported outcome in the studies (24 studies, 716 participants). Single interventions or series of treatments that continued for up to three 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 participants using PEP compared to other techniques when used with a mask for at least one year (five studies, 232 participants; 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 participants, low-quality evidence). Participant preference was reported in 10 studies; and in all studies with an intervention period of at least one month, this was in favor of PEP. The results for the remaining outcome measures (including 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 reported on adverse events; these were measured in five studies, two of which found no events. In a study where infants performing either PEP or PDPV experienced some gastroesophageal reflux, this was more severe in the PDPV group (26 infants, low-quality evidence). In PEP versus oscillating PEP, adverse events were only reported in the flutter group (five participants complained of dizziness, which improved after further instructions on device use was provided) (22 participants, low-quality evidence). In PEP versus HFCWO, from one long-term high-quality study (107 participants) 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 when compared to 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 also reported on all planned outcome measures. The authors concluded the evidence provided by this review is of variable quality, but suggests that all techniques and devices described may have a place in the clinical treatment of people with CF. Following meta-analyses of the effects of PEP versus other airway clearance techniques on lung function and patient preference, this Cochrane Review demonstrated that there was high-quality evidence that showed a reduction in pulmonary exacerbations when PEP using a mask was compared with HFCWO. Exacerbation rate and time to first exacerbation in longer term trials (at least 12 months) between compared airway clearance techniques may be of greater use and relevance in CF, a long-term disease.

Auger et al. (2017) conducted a systematic review to analyze twelve studies that examined the benefit and risk ratio for the use of mechanical insufflation-exsufflation (MI-E) devices for airway clearance in patients with neuromuscular diseases. The following inclusion criteria for outcomes was survival outcome, hospitalization rate, respiratory exacerbation outcome, pulmonary function parameters, adverse events, and quality of life. 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 patients with neuromuscular diseases as there is a lack of robust scientific evidence. Further research is necessary to ensure the best treatment for patients with neuromuscular disease.

In a cohort study comparing healthcare claims before and after initiation of HFCWO, Lechtzin et al. (2016) examined whether this modality leads to improved respiratory outcomes as measured by lower healthcare use for patients who have a chronic neuromuscular disease (NMD). Data were obtained from 2 large databases of commercial insurance claims. Study subjects (n = 426, pediatric and adult) were commercial insurance members with an International Classification of Diseases, Ninth Revision, code for a NMD 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, and similar results were found. The authors concluded that total medical costs, hospitalizations, and pneumonia claims were less after (versus before) initiation of HFCWO in a broad group of patients with NMD. 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 patients with NMD. These findings are limited by lack of concurrent comparison group undergoing a different therapeutic approach.

Lee et al. (2015) conducted a systematic review and meta-analysis to determine effects of airway clearance techniques (ACTs) on rates of acute exacerbation, incidence of hospitalization and health-related quality of life (HRQoL) in individuals with acute and stable bronchiectasis. Secondary: to determine whether: ACTs are safe for individuals with acute and stable bronchiectasis; and ACTs have beneficial effects on physiology and symptoms in individuals with acute and stable bronchiectasis. Cochrane Airways Group Specialized Register of trials from inception to November 2015 and PEDro in March 2015, were searched as well as hand-searched relevant journals. Randomized controlled parallel and cross-over trials that compared an ACT versus no treatment, sham ACT or directed coughing in participants with bronchiectasis were included in this review. Seven studies involving 105 participants met the inclusion criteria of this review, six of which were cross-over 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. 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 participants and personnel for outcome measure assessment. Heterogeneity between studies precluded inclusion of these data in the meta-analysis; the review is therefore narrative. One study including 20 adults that compared an airway oscillatory device versus 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 (SGRQ) score over three months in this study was 7.5 units [P value = 0.005 (Wilcoxon)]. Treatment consisting of high-frequency chest wall oscillation (HFCWO), or a mix of ACTs prescribed for 15 days improved HRQoL when 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% confidence interval (CI) 3.4 to 13.4 mL] and in the long term of 3 mL (P value = 0.02). HFCWO improved forced expiratory volume in one second (FEV1) 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-positive expiratory pressure (PEP) ACTs [difference in functional residual capacity (FRC) 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 FRC 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 effects of antibiotic usage. Among studies exploring 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 prescription of specific ACTs for people with bronchiectasis.

In a single-center, investigator initiated, prospective study of 22 subjects, 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 subjects were followed 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 45% of the subjects 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 of the number of hospital days at follow-up compared to pre-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 lack of concurrent comparison group undergoing a different therapeutic approach.

Nicolini et al. (2013) conducted as randomized controlled trial (RCT) to evaluate the effectiveness of treatment with high-frequency chest wall oscillation (HFCWO) in patients with bronchiectasis. The aim of this study was to find the more efficacious treatment in patients with bronchiectasis: traditional techniques of chest physiotherapy (CPT) versus high frequency oscillation of the chest wall in patients with bronchiectasis. A total of 37 patients were enrolled. Seven of them were excluded. Computer randomization divided the patients into three groups: - 10 patients treated with HFCWO by using the Vest® Airway Clearance System; - 10 patients treated with traditional techniques of air way clearance (PEP bottle, PEP mask, ELTGOL, vibratory positive expiratory pressure); - 10 patients 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: lack of informed consent, signs of exacerbation, cystic fibrosis. Before the treatment, each patient had blood tests, sputum volume and cell count, pulmonary function tests and on the quality-of-life inventories (MMRC, CAT, 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 the quality of life compared to the control group. The use of HFCWO compared to CPT also produced improvement in blood inflammation parameter C-RP ($p \leq 0.019$), parameters of lung functionality associated with bronchial obstruction (FVC, FEV1) ($p \leq 0.006$ and $p \leq 0.001$), and in the dyspnea. Improvement in quality-of-life scales was noted. (BCSS, CAT) (both $p \leq 0.001$). No changes of 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, and 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 patients with chronic hyper secretive disease. Since those patients need daily airway clearance, this treatment should be included among the principal options in chest physiotherapy. 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 clinical usefulness of this procedure is proven.

Yuan et al. (2010) conducted a prospective, RCT of HFCWC in pediatric patients with NMD or cerebral palsy (CP). Twenty-three patients (9 with CP and 14 with NMD) were randomized to receive either HFCWC or standard CPT. The mean study period was 5 months. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, chest x-ray and polysomnography. No significant changes were seen between the two groups for any of these outcome measures. Adherence to prescribed regimen was however higher with HFCWC ($p = 0.036$). The authors concluded that the data suggests safety, tolerability, and improved compliance with HFCWC but acknowledged that larger, controlled trials are needed to confirm results. Study limitations include small sample size, which could have resulted in not detecting clinically significant differences heterogenous nature of diagnoses and short-term follow-up.

Chaisson et al. (2006) conducted a randomized pilot study to evaluate the effectiveness of HFCWO administered through the Vest Airway Clearance System when added to standard care in preventing pulmonary complications and prolonging the time to death in patients with amyotrophic lateral sclerosis (ALS). Nine patients with a diagnosis of ALS and concurrently receiving non-invasive ventilatory support with bi-level positive airway pressure (BiPAP) were recruited from the outpatient clinic at a university medical center. Four patients received standard care and five patients received standard care plus the addition of HFCWO administered twice-daily for 15 min duration. Longitudinal assessments of oxyhemoglobin saturation forced vital capacity (FVC), and AEs were obtained until time of death. Pulmonary complications of atelectasis, pneumonia, hospitalization for a respiratory-related abnormality, and tracheostomy with mechanical ventilation were monitored throughout the study duration. No differences were observed between treatment groups in relation to the rate of decline in FVC. The addition of HFCWO airway clearance failed to improve time to death compared to standard treatment alone (340 days +/- 247 vs. 470 days +/- 241). The random allocation of HFCWO airway clearance to patients with ALS concomitantly receiving BiPAP failed to attain any significant clinical benefits in relation to either loss of lung function or mortality. The authors concluded that this study does not exclude the potential benefit of HFCWO in select patients with ALS who have coexistent pulmonary diseases, pre-existent mucus-related pulmonary

complications, or less severe levels of respiratory muscle weakness. The sample size may have been too small to detect clinically significant group differences.

An RCT evaluated the changes in respiratory function in patients with amyotrophic lateral sclerosis (ALS) after using HFCWC. Twenty-two patients received HFCWC, and 24 patients were untreated. HFCWC users had less breathlessness and coughed more at night at 12 weeks compared to baseline. The investigators concluded that HFCWC demonstrated a slowing of the decline of forced vital capacity. Limitations of this study include small patient numbers and lack of long-term follow-up. (Lange et al., 2006)

Combination Continuous Positive Expiratory Pressure (CPEP), Continuous High Frequency Oscillation (CHFO), and Nebulized Medication Therapy Devices for Oscillation and Lung Expansion (OLE)

Due to insufficient quality evidence or consistency of findings, combination CPEP, CHFO, and nebulized medication therapy devices for 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, exercise capacity) and acceptability (in terms of individual preference, adherence, quality of life) of conventional chest physiotherapy (CCPT) for people with cystic fibrosis (CF) compared to alternative airway clearance techniques (ACTs). The authors included randomized or quasi-randomized controlled trials (including cross-over design) lasting at least seven days and comparing CCPT with alternative ACTs in people with CF. Primary outcomes were 1. pulmonary function tests and 2. number of respiratory exacerbations per year. Secondary outcomes were 3. quality of life, 4. adherence to therapy, 5. cost-benefit analysis, 6. objective change in exercise capacity, 7. additional lung function tests, 8. ventilation scanning, 9. blood oxygen levels, 10. nutritional status, 11. mortality, 12. mucus transport rate, and 13. mucus wet or dry weight. Outcomes were reported as short-term (seven to 20 days), medium-term (more than 20 days to up to one year) and long-term (over one year). A total of 21 (778 participants) studies comprising seven short-term, eight medium-term and six long-term studies were included. Studies were conducted in the USA (10), Canada (five), Australia (two), the UK (two), Denmark (one) and Italy (one) with a median of 23 participants per study (range 13 to 166). Participant ages ranged from newborns to 45 years; most studies only recruited children and young people. Sixteen studies reported the sex of participants (375 males; 296 females). 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. Nineteen studies reported the primary outcomes forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) and found no difference in change from baseline in FEV1 % predicted or rate of decline between groups for either measure. Most studies suggested equivalence between CCPT and alternative ACTs, including positive expiratory pressure (PEP), extrapulmonary mechanical percussion, active cycle of breathing technique (ACBT), oscillating PEP devices (O-PEP), autogenic drainage (AD) and exercise. Where single studies suggested superiority of one ACT, these findings were not corroborated in similar studies; pooled data generally concluded that effects of CCPT were comparable to those of alternative ACTs. CCPT versus 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. CCPT versus 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 (FEF25-75) was greater with high-frequency chest compression compared to CCPT in medium- to long-term studies, but there was no difference in any other outcome. CCPT versus ACBT: The authors are uncertain whether CCPT improves lung function compared to ACBT (very low-certainty evidence). Annual decline in FEF25-75 was worse in participants using the FET component of ACBT only [mean difference (MD) 6.00, 95% confidence interval (CI) 0.55 to 11.45; 1 study, 63 participants; 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. CCPT versus O-PEP: The authors are uncertain whether CCPT improves lung function compared to O-PEP devices (Flutter device and intrapulmonary percussive ventilation); however, only one study provided analyzable data (very low-certainty evidence). No study reported data for number of exacerbations. There was no difference in results for 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. CCPT versus AD: The authors are uncertain whether CCPT improves lung function compared to AD (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 to 0.42; 33 participants). One study provided a narrative report of a preference for AD. CCPT versus exercise: The authors are uncertain whether CCPT improves lung function compared to exercise (very low-certainty evidence). Analysis of original

data from one study demonstrated a higher FEV1 % predicted (MD 7.05, 95% CI 3.15 to 10.95; p = 0.0004), FVC (MD 7.83, 95% CI 2.48 to 13.18; p = 0.004) and FEF25-75 (MD 7.05, 95% CI 3.15 to 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 when compared to 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 participants 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 CF 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 (CF). Search criteria included randomized controlled studies 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. The searches identified 82 studies (330 references); 39 studies (total of 1114 participants) met the inclusion criteria. Studies varied in duration from up to one week to one year; 20 of the studies were cross-over 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 participants 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. Forced expiratory volume in one second was the most frequently measured outcome and while many of the studies reported an improvement in those people using a vibrating device compared to before the study, there were few differences when comparing the different devices to each other or to other airway clearance techniques. One study identified an increase in frequency of exacerbations requiring antibiotics whilst using high frequency chest wall oscillation when compared to positive expiratory pressure (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. Participant 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 participants 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 is superior to another. The findings from one study showing an increase in frequency of exacerbations requiring antibiotics whilst using an oscillating device compared to positive expiratory pressure may have significant resource implications. More adequately powered long-term randomized controlled trials are necessary and 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 is 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 airway clearance techniques. 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 generated by future interventions.

Huynh et al. (2019) conducted a multicenter, non-randomized prospective study to examine the impact of oscillation and lung expansion (OLE) therapy, using continuous high-frequency oscillation and continuous positive expiratory pressure on post-operative pulmonary complications (PPCs) in high-risk patients. In stage I, CPT and ICD codes were queried for patients (n = 210) undergoing thoracic, upper abdominal, or aortic open procedures at 3 institutions from December 2014 to April 2016. Patients were selected randomly. Age, comorbidities, American Society of Anesthesiologists physical status classification scores, and PPC rates were determined. In stage II, 209 subjects were enrolled prospectively from October 2016 to July 2017 using the same criteria. Stage II subjects received OLE treatment and standard respiratory care. The PPCs rate (prolonged ventilation, high-level respiratory support, pneumonia, ICU readmission) were compared. The authors also compared ICU length of stay (LOS), hospital LOS, and mortality using t-tests and analysis of covariance. Data are mean ±SD. There were 419 subjects. Stage II patients 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 LOS (8.4 ±7.9 days to 6.8 ±5.0 days; p < 0.05). No differences in ICU LOS, pneumonia, or mortality were observed. The authors

concluded that aggressive treatment with OLE reduces PPCs and resource use in high-risk surgical patients. Well designed, adequately powered, prospective, controlled clinical trials of combination OLE treatment are needed to further describe safety and clinical efficacy.

Intrapulmonary Percussive Ventilation (IPV)

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

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

Hassan et al. (2021) performed a systematic review to summarize the evidence of the effectiveness of intrapulmonary percussive ventilation (IPV) on intensive care unit length of stay (ICU-LOS) and respiratory outcomes in critically ill patients. A systematic search of IPV in intensive care units (ICU) was performed on five databases from 1979 to 2021. Studies were considered for inclusion if they evaluated the effectiveness of IPV in patients aged ≥ 16 years receiving invasive or non-invasive ventilation or 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 patient population, a meta-analysis could not be included in this review. Out of 306 identified abstracts, seven studies (630 patients) met the eligibility criteria. Results of the included studies provide weak evidence to support the effectiveness of IPV in reducing ICU-LOS, 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-LOS, 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 (7). Heterogeneities resulting from differences in study design, patient population, dosage, and frequency of IPV intervention were frequently observed in the included studies. Further, small sample sizes and poor methodological quality introduces some bias and weakens the strength of conclusions of this review. Further investigation is needed before clinical usefulness of this procedure is proven.

Nicolini et al. (2018) conducted a four-week RCT to determine if adding Intrapulmonary percussive ventilation (IPV) or high-frequency chest wall oscillation (HFCWO) with the best pharmacological therapy (PT) will provide clinical benefit to patients with chronic obstructive pulmonary disease (COPD) over just chest physiotherapy (CPT). There was a total of 63 patients randomized into three groups (20 patients 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). Primary outcomes measured are the dyspnea scale [modified Medical Research Council (mMRC)] and Breathlessness, Cough, and Sputum scale (BCSS), along with daily life activity [COPD Assessment Test (CAT)]. Secondary outcomes measured are pulmonary function testing (PFT), arterial blood gas analysis, and hematological examinations. Patients in both the IPV and HFCWO group showed marked improvement in dyspnea and mMRC, BCSS and CAT compared to the control group. IPV patients showed an improvement in BCSS (p = 0.001) and CAT (p = 0.02) scores in comparison with HFCWO. Both IPV and HFCWO secondary outcomes improved compared to 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 total lung capacity (TLC) and TLC% (p = 0.03), residual volume (RV) and RV% (p = 0.04), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal lung capacity (MEP, p = 0.01). The authors concluded that both IPV and HFCWO can improve lung function, muscular strength, dyspnea, and overall health status. and that IPV demonstrated better effectiveness in improving test results in small bronchial airways and alveolar ventilation (RV and DLCO) and muscular strength (MIP and MEP) as well as scores on daily life activity and health status assessment scales (BCSS and CAT) compared with HFCWO. A multi-center, larger population study with measurement of primary and secondary outcomes over a longer term is needed. Limitations of this study included single center, small sample size and , short duration and lack of masking or 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 related to the use of IPV as an airway clearance technique in chronic obstructive airway diseases. Using predetermined criteria, a search was conducted in PubMed, PEDro, and Scopus online databases. Outcomes of interest included immediate or prolonged physiological effects (e.g., gas exchange, cardiorespiratory parameters, lung function, and mechanics) and clinical effects (e.g., symptoms, adverse effects, and length of hospital stay). A total of 109 studies were identified and after further evaluation, 12 studies were included in the review. Of those, 1 study evaluated patients with bronchiectasis (n = 22), 4 studies evaluated patients with cystic fibrosis (n = 78), and 6 studies (1 study included phase I and 2 results) evaluated patients with COPD (n = 178). In patients with COPD, IPV improved gas exchange during exacerbation and reduced the hospital length of stay however, IPV was no more beneficial than other airway clearance techniques when subjects were stable. Two studies reported complications or discomfort with IPV and in another study, 2 patients did not tolerate settings with a higher frequency of percussions (1.220 cm H2O-350 c/min and 1.840 cm H2O-350 c/min). In patients with CF, cardiorespiratory parameters and lung function did not improve with IPV. One study reported mild hemoptysis, which was associated with a respiratory infection. In patients with bronchiectasis, dyspnea and respiratory frequency improved after 1 session of IPV however, there was no difference in sputum dry weight and in patients with productive bronchiectasis, immediate efficacy of IPV vs. other airway clearance techniques did not differ. Minor adverse events (dry throat, nausea, and/or fatigue) were reported in 27% of patients treated with both IVP and chest physical therapy. The authors concluded that use of IPV as an airway clearance technique in chronic obstructive airway diseases is not supported by sufficiently strong evidence to recommend routine use in this patient population.

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 ALS. (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 (CF) and other causes by using non-pharmacological 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 question, "Is there evidence of clinically important treatment effects for non-pharmacological therapies in cough treatment for patients with bronchiectasis?" Populations selected were all patients with bronchiectasis due to CF or non-CF bronchiectasis. The interventions explored were the non-pharmacological airway clearance therapies. The comparison populations included those receiving standard therapy and/or placebo. Clinically important outcomes that were explored were exacerbation rates, quality of life, hospitalizations, and mortality. In both CF and non-CF bronchiectasis, there were systematic reviews and overviews of systematic reviews identified. Despite these findings, there were no large randomized controlled trials (RCTs) that explored the impact of airway clearance on exacerbation rates, quality of life, hospitalizations, or mortality. The authors concluded there is insufficient evidence that any airway clearance technique is consistently more effective than any other for clinically important outcomes in CF 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 predicated upon 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 employ those techniques early and aggressively.

ATS makes the following recommendations:

- Use assisted cough technologies in patients whose clinical history suggests difficulty in airway clearance, or whose peak cough flow is less than 270 L/minute and/or whose maximal expiratory pressures are less than 60 cm H2O.
- The committee strongly supports use of mechanical insufflation-exsufflation in patients with DMD and also 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 needing hospitalization. (Finder et al., 2004)

National Institute for Health and Care Excellence (NICE)

In a 2018 MedTech innovation briefing, the National Institute for Health and Care Excellence (NICE) found no published guidelines on airway clearance in people with complex neurological needs.

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 September 18, 2024)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0052JJ]

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Policy History/Revision Information

Date	Summary of Changes
03/01/2025	**Coverage Rationale** • Added language to indicate combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary **Applicable Codes** • Added HCPCS codes A7021 and E0469 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version DME 019.40

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.