

Airway Clearance Devices (for North Carolina Only)

Policy Number: CSNCT0700.01
Effective Date: July 1, 2021

[Instructions for Use](#)

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Related Policy

- [Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements](#)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

High-frequency chest wall oscillation system is proven and medically necessary in the management of pulmonary conditions characterized by the production of excessive airway secretions, infection and inadequate airway clearance. For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy for Medical Equipment, 5A-2 Respiratory Equipment and Supplies](#).

The oscillatory positive expiratory pressure (PEP) device and the Flutter device facilitate secretion removal is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the [North Carolina Medicaid \(Division of Health Benefits\) Clinical Coverage Policy for Medical Equipment, 5A-2 Respiratory Equipment and Supplies](#).

An acoustical or mechanical percussor, positive expiratory pressure and aerosol drug delivery system combination device (e.g., Vibralong®) is considered Medically Necessary in the management of airway clearance.

An acoustical percussor is Medically Necessary when both of the following criteria are met:

- A diagnosis of CF, bronchiectasis, or immotile cilia syndrome with bronchiectasis that is characterized by excessive mucus production, infection and difficulty clearing secretions
- Failure, intolerance or contraindication to a standard airway clearance device (e.g., mechanical percussor, positive expiratory pressure device, oscillatory device, high-frequency chest wall compression device) due to chest wall injury (e.g., fractured ribs, burns).

An intrapulmonary percussive ventilation (IPV) device for home use is considered unproven and not Medically Necessary. An IPV (E0481) 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.

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.

HCPSC Code	Description
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussive ventilation system and related accessories
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

Diagnosis Code	Description
E84.9	Cystic fibrosis, unspecified
E84.0	Cystic fibrosis with pulmonary manifestations
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
Q33.4	Congenital bronchiectasis

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 or increased viscosity of secretions. 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.

Additional Information

Bronchiectasis is defined as a daily productive cough for at least 6 continuous months or exacerbations requiring antibiotic therapy more than two times per year, and confirmed by high resolution, spiral, or standard computed tomography (CT) scan, and well-documented failure of standard treatments to adequately mobilize retained secretions.

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

Cystic Fibrosis (CF) and Bronchiectasis

Hayes identified and reviewed 18 studies that evaluated HFCWC for treatment of CF. The available evidence from several comparative and crossover studies indicates that HFCWC may be comparable to other airway clearance therapies with regard to lung function and sputum expectoration in CF patients. However, the long-term impact of HFCWC devices on functional outcomes has not been adequately studied. These factors, along with potential safety issues observed in recent randomized studies, renders HFCWC less of an initial and primary treatment option, and more as a possible component of an individualized and comprehensive treatment plan (2019).

In a Cochrane review, McIlwaine et al. (2015) compared positive expiratory pressure (PEP) devices to other forms of physiotherapy as a means of improving mucus clearance and other outcomes in people with CF. A total of 26 studies (involving 733 participants) were included in the review. Eighteen studies involving 296 participants were cross-over in design. Studies had to include one or more of the following outcomes: change in forced expiratory volume in one second; number of respiratory exacerbations; a direct measure of mucus clearance; weight of expectorated secretions; other pulmonary function parameters; a measure of exercise tolerance; ventilation scans; cost of intervention; and adherence to treatment. Following meta-analysis, it was concluded that the use of PEP resulted in a significant reduction in pulmonary exacerbations in individuals where exacerbation rate was a primary outcome measure.

In a Cochrane review, Lee et al. (2013) evaluated the effects of various airway clearance therapies (ACTs) on the rate of acute exacerbations, incidence of hospitalization and health-related quality of life (QOL) in individuals with acute and stable bronchiectasis. HFCWC was one of the ACTs included. Randomized controlled parallel and cross-over trials that compared an ACT to no treatment, sham ACT or directed coughing were utilized. Five studies involving 51 participants met the inclusion criteria. The authors concluded that ACTs appear to be safe for adults and children with stable bronchiectasis, where there may be improvements in sputum expectoration, selected measures of lung function and health-related QOL. The role of these techniques in people with an acute exacerbation of bronchiectasis is unclear. More data are needed to establish the clinical value of ACTs over the short and long term on patient outcomes which may clarify the rationale for each technique. A 2015 update of this review resulted in no changes to the original conclusions.

Nicolini et al. (2013) compared traditional techniques of CPT with HFCWO in patients with bronchiectasis. Participants were randomized into three groups: HFCWO (n=10), PEP (n=10) and a control group of medical therapy only (n=10). The authors reported that both HFCWO and PEP showed a significant improvement in pulmonary function and QOL.

Fainardi et al. (2011) compared the short-term efficacy of HFCWC and PEP mask on expectorated sputum, pulmonary function and oxygen saturation in individuals hospitalized for an acute pulmonary exacerbation of CF. A controlled randomized cross-over trial with 24 hours between treatments was used. Thirty-four CF patients (26 ± 6.5 years) were included in the study. No statistically significant difference between HFCWC and PEP was found in sputum production and in lung function testing. Although PEP was associated with lower oxygen saturation, it was better tolerated than HFCWC.

The Cystic Fibrosis Foundation commissioned a systematic review to examine the evidence surrounding the use of ACTs for treating CF. Seven unique reviews and 13 additional controlled trials were deemed eligible for inclusion. Recommendations for

use of the ACTs were made, balancing the quality of evidence and the potential harms and benefits. The committee determined that, although there is a paucity of controlled trials that assess the long-term effects of ACTs, the evidence quality overall for their use in CF is fair and the benefit is moderate. The committee recommends airway clearance be performed on a regular basis in all patients. There are no ACTs demonstrated to be superior to others, so the prescription of ACTs should be individualized (Flume et al., 2009).

In a Cochrane review, Morrison and Agnew (2009) evaluated the effectiveness and acceptability of oscillating devices compared to other forms of physiotherapy to improve respiratory function, mucus clearance and other outcomes in people with CF. Out of 265 identified studies, 30 met the inclusion criteria (n=708). The authors noted that data were not published in sufficient detail in most of the studies to perform a meta-analysis. Forced expiratory volume in one second (FEV1) was the most frequently measured outcome. Results did not show significant difference in effect between oscillating devices and other methods of airway clearance on FEV1 or other lung function parameters. Where there has been a small but significant change in secondary outcome variables such as sputum volume or weight, this has not been wholly in favor of oscillating devices. Participant satisfaction was reported in 11 studies, but this was not specifically 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 or that one device is superior to another. More adequately-powered long-term randomized controlled trials (RCTs) are needed. A 2017 update resulted in the same conclusions.

Other Conditions

In a Medical Technology Impact Comparison of HFCWC for diseases other than CF, Hayes reviewed a total of 13 studies and concluded that HFCWC may provide some therapeutic benefit in adult patients and in children with disorders of airway clearance not related to CF. Positive but very limited evidence suggests that HFCWC can also be effective and safe in children with non-CF diagnoses. However, additional studies are needed to confirm this preliminary evidence. The quality of evidence is considered low due to small sample size and/or lack of statistical power, short duration of treatment and follow-up, and lack of or failure to report blinding in most studies (2014; archived 2019).

In a 2019 custom product brief on The Vest Airway Clearance System, ECRI identified and reviewed one international single-blind RCT (n=73), one international open label RCT (n=50), and one 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.

Nicolini et al. (2018) tested the hypothesis that adding IPV or HFCWO to the best pharmacological therapy may provide additional clinical benefit over chest PT in patients with severe COPD. Participants (n=60) were randomized equally into three groups: IPV group (treated with pharmacotherapy and IPV), HFCWO group with (treated with pharmacotherapy and HFCWO), and control group (treated with pharmacotherapy alone). Primary outcome measures included results on the dyspnea scale (modified Medical Research Council) and Breathlessness, Cough, and Sputum scale (BCSS), as well as an evaluation of daily life activity (COPD Assessment Test [CAT]). Secondary outcome measures were PFTs, ABG analysis, and hematological examinations. Additionally, sputum cell counts were performed at the beginning and at the end of the study. Compared to the control group, patients in both of the combination therapy groups showed a significant improvement in dyspnea and daily life activity evaluations, as well as in PFTs (forced vital capacity, forced expiratory volume in one second, forced expiratory volume in one second/forced vital capacity %, total lung capacity, residual volume, diffusing lung capacity monoxide, maximal inspiratory pressure, maximal expiratory pressure) and ABG values. However, when comparing the IPV and HFCWO groups using the same outcome measures, a significant improvement in the IPV group maximal inspiratory pressure, maximal expiratory pressure, BCSS, and CAT, as well as changes of sputum cytology with reduction of inflammatory cells (neutrophils and macrophages) was observed. The authors concluded that the two techniques improved daily life activities and lung function in patients with severe COPD. IPV demonstrated a significantly greater effectiveness in improving some PFTs linked to the small

bronchial airway obstruction and respiratory muscle strength and scores on health status assessment scales as well as a reduction of sputum inflammatory cells compared with HFCWO.

In bronchiectasis due to CF and other causes, airway clearance is one of the mainstays of management. Hill and colleagues (2018) conducted a systematic review on airway clearance by using non-pharmacological ACTs as recommended by international guidelines to develop recommendations or suggestions to update the 2006 CHEST guideline on cough. Populations selected were all patients with bronchiectasis due to CF or non-CF conditions. The comparison populations included those receiving standard therapy and/or placebo. Outcome measures included exacerbation rates, QOL, hospitalizations, and mortality. In both CF and non-CF bronchiectasis, there were systematic reviews and overviews of systematic reviews identified but large RCTs were not found. The researchers stated that airway clearance research in these patient populations has been underwhelming due to the lack of adequately powered RCTs. These trials are challenging, as ideally the comparator arm would be no physiotherapy, making the studies difficult to blind and leading to ethical challenges, as airway clearance is regarded as standard care. This has led to underpowered comparator studies of one technique vs another technique. Future studies assessing the optimum method, duration, and frequency for long-term (> 28 days) airway clearance with clinically important outcomes are needed as well as the optimum target group. While they were not able to make recommendations, the panel made the following ungraded consensus-based suggestions: 1. For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that they be taught airway clearance techniques by professionals with advanced training in airway clearance techniques; 2. For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that the frequency of airway clearance should be determined by disease severity and amount of secretions; 3. For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that airway clearance techniques are individualized as there are many different techniques.

An observational RCT by Chuang and colleagues (2017) sought to investigate the effect of HFCWO on pneumonic subjects with acute respiratory failure receiving mechanical ventilation by evaluating immediate cardiopulmonary changes and changes in the initial ventilator settings caused by oscillation. Patients (n=73) who were intubated with mechanical ventilated were recruited and randomly classified into two groups (HFCWO group, N=36; and control group who received conventional chest physical therapy (CCPT, n=37). HFCWO was applied with a fixed protocol, whereas CCPT was conducted using standard protocols. Both groups received sputum suction after the procedure. Changes in ventilator settings and the subjects' responses were measured at preset intervals and compared within groups and between groups. Results demonstrated that while changes in tidal volume between baseline and after sputum suction for 15 minutes were not significant in either group, CCPT seemed more efficacious for tidal volume before and after sputum suction. The authors concluded that HFCWO affects breathing pattern and SpO₂ but not ventilator settings, whereas CCPT maintains a steadier condition. After sputum suction, HFCWO slightly improved peak airway pressure compared to CCPT, suggesting that the study extends the indications of HFCWO for these patients in the intensive care unit (ClinicalTrials.gov number NCT02758106).

In a single-center, investigator initiated, prospective study of 22 subjects, Fitzgerald et al. 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 (2014).

Gokdemir et al. conducted a controlled randomized crossover study to compare the efficacy and safety of conventional pulmonary rehabilitation (CPR) versus HFCWO in the pulmonary function of pediatric patients with primary ciliary dyskinesia (PCD). Patients between the ages of 7 and 18 years were assigned to 2 groups. The first group performed airway clearance with CPR at hospital for five days; and after a two-day washout period, HFCWO was applied to the same group at home. The second group received HFCWO first and then were hospitalized for CPR. The primary outcome measure of the study was pulmonary function test (PFT). The secondary outcomes were pulse arterial oxygen saturation (SpO₂) and the perceived efficiency and comfort level. PFTs were significantly increased after both methods. There were no differences in PFTs and SpO₂ between the two groups, and both methods were found to be efficient. However, HFCWO was found more to be comfortable. The authors concluded that HFCWO may be an option in patients with chronic pulmonary disease and low adherence to pulmonary rehabilitation (2014).

Huang et al. (2016) evaluated the effectiveness, safety and tolerance of HFCWC after extubation in prolonged mechanical ventilation (PMV) patients. Forty-three participants were randomly assigned to either receive HFCWC for five days (n=23) or not (n=20). Effectiveness was based on weaning success rates, daily clearance volume of sputum, serial changes in sputum coloration and chest X-ray (CXR) improvement rates. The weaning success rates were 82.6% (19/23) and 85% (17/20) in the HFCWC and non-HFCWC groups, respectively. The HFCWC group had persistently greater numbers of daily sputum suction and higher CXR improvement rates compared with the non-HFCWC group. There was significant sputum coloration lightening in the HFCWC group only. In PMV patients, HFCWC was safe, comfortable and effective in facilitating airway hygiene after removal of endotracheal tubes but had no positive impact on weaning success.

Clinkscale et al. (2012) compared the overall effectiveness of conventional CPT to HFCWC in hospitalized intubated and non-intubated adult patients requiring CPT. The primary outcome measure was hospital stay. A total of 280 patients were randomly assigned to receive CPT (n=146) or HFCWC (n=134). The hospital stay was 12.5 ± 8.8 days for patients randomized to CPT and 13.0 ± 8.9 days for patients randomized to HFCWC. Patient comfort was assessed using a visual analog scale and was statistically greater for patients randomized to CPT compared to HFCWC. All other secondary outcomes, including hospital mortality and nosocomial pneumonia, were similar for both treatment groups. The authors reported that because the study was inadequately powered for the primary outcome, they could not make recommendations on the preferential use of HFCWC or CPT for intubated and non-intubated adult patients.

In a cohort study comparing healthcare claims before and after initiation of HFCWO, Lechtzin et al. 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 two 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 not were compared, 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 (2016).

In an effort to evaluate the use of HFCWO early in the treatment of adults hospitalized for acute asthma or chronic obstructive pulmonary disease (COPD), Mahajan et al. conducted a multi-center, double-masked phase II RCT of active or sham treatment initiated within 24 hours of hospital admission. Patients received active (n=25) or sham (n=27) treatment for 15 minutes three times a day for four treatments. Medical management was standardized across groups. The primary outcomes were patient adherence to therapy after four treatments (minutes used/60 minutes prescribed) and satisfaction. Secondary outcomes included change in Borg dyspnea score (≥ 1 unit indicates a clinically significant change), spontaneously expectorated sputum volume, and forced expired volume in one second. Patient adherence was similarly high in both groups (91% vs. 93%) and patient satisfaction was also similarly high in both groups. After four treatments, a higher proportion of patients in the active treatment group had a clinically significant improvement in dyspnea (70.8% vs. 42.3%). There were no significant differences in other secondary outcomes. The authors concluded that HFCWO is well tolerated in adults hospitalized for acute asthma or COPD and significantly improves dyspnea. The high levels of patient satisfaction in both treatment groups justify the need for sham controls when evaluating the use of HFCWO on patient-reported outcomes. Additional studies are needed to more fully evaluate the role of HFCWO in improving in-hospital and post-discharge outcomes in this population (2011).

Yuan et al. (2010) conducted a prospective, RCT of HFCWC in pediatric patients with NMD and 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 five months. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, CXR and polysomnography. No significant changes were seen between the two groups for any outcome measure. 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, heterogeneous 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. 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.

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).

Another study evaluated the impact of HFCWC vest therapy in a group of seven pediatric nursing home patients with quadriplegic CP and a history of frequent pulmonary infections. The total number of pneumonias, hospitalizations due to pneumonia, the frequency of effective suctioning, and the average monthly frequency of seizures in patients with epilepsy were recorded during the period of HFCWC vest therapy and then compared with data from the previous year. There were improvements in all of the measured parameters during the 12 months of vest therapy, although only the reduction in number of pneumonias and the improvement in number of effective suctioning episodes reached statistical significance, likely due to the very small sample size. Definitive conclusions regarding the relative efficacy of HFCWC vest therapy and conventional CPT cannot be drawn from this study, since the frequency and protocol for CPT administered to these patients prior to HFCWC therapy were highly variable, and the sample size was so small. The investigators noted a reduction in staff time required for respiratory therapy during the HFCWC vest therapy study period (Plioplys et al., 2002).

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.

There are open clinical trials studying high frequency chest wall oscillation in multiple clinical scenarios. For more information, refer to www.clinicaltrials.gov. (Accessed August 25, 2020)

Vibralong®

Courtney M Wheatley et al., conducted two randomized controlled trials, 10 and 11 mild to moderate CF patients were recruited for study I and II, respectively. Study I: Vibralong was used for 20 minutes with either no sound (NS: PEP only) or sound (S: PEP and sound) on randomized visits. Pulmonary function, diffusion capacity of the lungs for carbon monoxide and nitric oxide (DL_{CO}/DL_{NO}), symptoms, and peripheral oxygen saturation (SpO_2) were measured at baseline and at one and four hours post treatment. Expecterated sputum was collected over four hours post treatment. Study II: over five days of in-hospital therapy, the Vibralong or vibratory vest therapy (Vest) were used for two therapy sessions per day, with sputum collected for 20 minutes following each therapy and pulmonary function accessed pre and post each five-day period (days 1-5 or 7-11) in a randomized crossover design. Vibralong usage resulted in no change from baseline to four hours post in pulmonary function, SpO_2 or symptoms ($p > 0.05$). At 4 h post therapy, the DLCO- and DLNO-derived measure of alveolar-capillary unit function (DM/ VC) showed improvement (DM/ VC = 12.5 ± 5.5 versus $7.3 \pm 18.8\%$ change, S versus NS) with no difference between S and NS ($p = 0.74$). Sputum expectoration was similar between S and NS conditions (wet sputum = 10.5 ± 4.6 versus 9.9 ± 3.2 g, S versus NS, $p = 0.25$). There were no differences in the improvement in pulmonary function between Vibralong and Vest during either 5-day period during the hospital stay. Vibralong was well tolerated and caused no detrimental changes in pulmonary function metrics. The Vibralong appears to be a safe airway clearance therapy (ACT) in individuals with CF.

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)

The ACCP indicates that devices designed to oscillate gas in the airway (e.g., Flutter, IPV, HFCWC), either directly or by compressing the chest wall, may be considered an alternative to CPT in patients with CF (level of evidence, low; benefit, conflicting; grade of recommendation, inconclusive) (McCool and Rosen, 2006).

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).

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 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/pmnm.cfm>. (Accessed August 25, 2020)

Additional Product Information

- The Vest[®] Airway Clearance System
- SmartVest[®] Airway Clearance System
- inCourage[®] System
- Monarch[®] Airway Clearance System

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	<ul style="list-style-type: none">New Medical Policy

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, please 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.