

HIGH FREQUENCY CHEST WALL COMPRESSION DEVICES

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Related Commercial Policy
<ul style="list-style-type: none"> Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements

Community Plan Policy
<ul style="list-style-type: none"> High Frequency Chest Wall Compression Devices

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, 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 MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

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, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

High-frequency chest wall compression (HFCWC), as a form of chest physical therapy, is proven and medically necessary for treating or preventing pulmonary complications of the following conditions:

- Cystic fibrosis (CF)
- Bronchiectasis

HFCWC is unproven and not medically necessary for any other condition due to insufficient evidence of efficacy.

Note: There are multiple airway clearance techniques currently used in the management of CF and bronchiectasis. These can include percussion and postural drainage, huffing, active cycle breathing and intrapulmonary percussive ventilation (IPV).

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 Coverage Determination Guidelines may apply.

HCPCS 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
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

ICD-10 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 2 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.

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 (2017).

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 (ACT) 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 unknown. 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; updated 2018).

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 3 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 1 second, forced expiratory volume in 1 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 2 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 airways 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 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).

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 5 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 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 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).

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 5 months. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, CXR and polysomnography. No significant changes were seen between the 2 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, heterogenous nature of diagnoses and short-term follow-up.

A 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 7 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).

There are open clinical trials studying high frequency chest wall oscillation in multiple clinical scenarios. For more information, please go to www.clinicaltrials.gov.

Professional Societies

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 Association for Respiratory Care (AARC)

AARC clinical practice guidelines on nonpharmacologic airway clearance therapies in hospitalized patients state that, due to insufficient evidence, HFCWC cannot be recommended for adult or pediatric patients with NMD, respiratory muscle weakness or impaired cough (Strickland et al., 2013).

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)

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. See the following website for more information (use product code BY1):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>. (Accessed June 1, 2018)

Additional Product Information

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers high frequency chest wall compression (HFCWC) when criteria are met. Refer to the Local Coverage Determinations (LCDs) for High Frequency Chest Wall Oscillation Devices. (Accessed June 7, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> Updated list of applicable HCPCS codes to reflect annual code edits; revised description for E0483 Archived previous policy version 2018T0052U