Airway Clearance Devices (for Kentucky Only)

Policy Number: CS054KY.12
Effective Date: April 1, 2024

Ü Instructions for Use

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Related Policy

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

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Airway clearance devices are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Airway or Secretion Clearance Devices.

Click here to view the InterQual® criteria.

For neuromuscular disorders, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) – UHG.

Click here to view the InterQual® criteria.

For neuromuscular disorders, an initial three-month rental trial for must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined.

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
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
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

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.

Clinical Evidence

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

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 (P 5 .004) 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 (P 5 .009). 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 trail (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 were not 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 RCT, 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 ≤ 0.019), parameters of lung functionality associated with bronchial obstruction (FVC, FEV1) (P ≤ 0.006 and P ≤ 0.001), and in the dyspnea. Improvement in quality-of-life scales was noted. (BCSS, CAT) (both P ≤ 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 ≤ 0.002) was noted, and an increase of macrophages percentage (P ≤ 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).

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 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 26, 2023)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2024	**Coverage Rationale** • Added language pertaining to treatment of **neuromuscular disorders** to indicate: o For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) – UHG o An initial three-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined **Applicable Codes** • Removed list of applicable ICD-10 diagnosis codes: A80.0, A80.1, A80.2, A80.30, A80.39, A80.4, A80.9, B91, E74.02, E74.4, E84.0, E84.9, G12.0, G12.1, G12.9, G12.21, G12.22, G12.25, G12.8, G14, G35, G71.00, G71.11, G71.20, G71.21, G71.220, G71.228, G71.29, G71.3, G71.8, G72.41, G72.89, G73.1, G73.3, G73.7, G80.0, G82.50, G82.51, G82.52, G82.53, G82.54, J47.0, J47.1, J47.9, J98.6, M33.02, M33.12, M33.22, M33.92, M34.82, M35.03, Q33.4, R53.2, and Z99.11 **Supporting Information** • Added *Clinical Evidence* and *References* sections • Archived previous policy version CS054KY.11

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.

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