

Airway Clearance Devices (for Nebraska Only)

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[Instructions for Use](#)

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Related Policy

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

Application

This Medical Policy only applies to the state of Nebraska.

Coverage Rationale

A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met:

- A confirmed diagnosis of one of the following neuromuscular diseases:
 - Quadriplegia
 - Muscular dystrophy
 - Multiple sclerosis
 - Polio or post-polio syndrome
 - Other anterior horn cell disease
 - Myotonic disorder or other myopathy
 - Paralysis of the diaphragm
 - Acid maltase deficiency
 - Amyotrophic lateral sclerosis (ALS)
 - Spinal muscular atrophy (SMA); and
- Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year); and
- Failure of standard treatments to adequately mobilize retained secretions

A two-month rental trial of a high-frequency chest wall oscillation system is proven and Medically Necessary in the management of bronchiectasis and, cystic fibrosis, which are characterized by the production of excessive airway secretions, infection, and inadequate airway clearance when criteria have been met. For additional medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Secretion Clearance Devices.

Click [here](#) to view the InterQual® criteria.

For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For Medical Necessity determination to address ongoing use, refer to the InterQual Criteria.

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

Definitions

Bronchiectasis: Dilation, (ectasia) of the airways or bronchi, with primary clinical manifestations of recurrent, chronic, or refractory infections. Confirmatory symptoms/clinical manifestations include a daily productive cough for at least six continuous months or exacerbations requiring antibiotic therapy more than two times per year and a progression to well-documented failure of standard treatments to adequately mobilize retained secretions. The presence of bronchiectasis is confirmed and classified radiographically, by high resolution, spiral, or standard computed tomography (CT) scan.

Medically Necessary: Health care services that are all of the following as determined by UnitedHealthcare or our designee:

- In accordance with Generally Accepted Standards of Medical Practice
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms
- Not mainly for the member's convenience or that of the member's doctor or other health care provider
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the member's Sickness, Injury, disease, or symptoms

Generally Accepted Standards of Medical Practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes.

If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. UnitedHealthcare has the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be determined by UnitedHealthcare.

UnitedHealthcare develops and maintains clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting UnitedHealthcare's determinations regarding specific services. These clinical policies (as developed by UnitedHealthcare and revised from time to time), are available to Covered Persons through www.myuhc.com or the telephone number on the member's ID card. They are also available to Physicians and other health care professionals on UHCprovider.com.

Applicable Codes

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

HCPCS Code	Description
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, includes all accessories and supplies, each

Diagnosis Code	Description
A80.0	Acute paralytic poliomyelitis, vaccine-associated
A80.1	Acute paralytic poliomyelitis, wild virus, imported
A80.2	Acute paralytic poliomyelitis, wild virus, indigenous
A80.30	Acute paralytic poliomyelitis, unspecified
A80.39	Other acute paralytic poliomyelitis
A80.4	Acute nonparalytic poliomyelitis
A80.9	Acute poliomyelitis, unspecified
B91	Sequelae of poliomyelitis
E74.02	Pompe disease
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E84.0	Cystic fibrosis with pulmonary manifestations
E84.9	Cystic fibrosis, unspecified
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.25	Progressive spinal muscle atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Postpolio syndrome
G35	Multiple sclerosis
G71.00	Muscular dystrophy, unspecified
G71.11	Myotonic muscular dystrophy
G71.20	Congenital myopathy, unspecified
G71.21	Nemaline myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G71.3	Mitochondrial myopathy, not elsewhere classified
G71.8	Other primary disorders of muscles
G72.41	Inclusion body myositis [IBM]
G72.89	Other specified myopathies
G73.1	Lambert-Eaton syndrome in neoplastic disease
G73.3	Myasthenic syndromes in other diseases classified elsewhere
G73.7	Myopathy in diseases classified elsewhere
G80.0	Spastic quadriplegic cerebral palsy
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
J47.0	Bronchiectasis with acute lower respiratory infection

Diagnosis Code	Description
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
J98.6	Disorders of diaphragm
M33.02	Juvenile dermatomyositis with myopathy
M33.12	Other dermatomyositis with myopathy
M33.22	Polymyositis with myopathy
M33.92	Dermatopolymyositis, unspecified with myopathy
M34.82	Systemic sclerosis with myopathy
M35.03	Sicca syndrome with myopathy
Q33.4	Congenital bronchiectasis
R53.2	Functional quadriplegia
Z99.11	Dependence on respirator [ventilator] status

Description of Services

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

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

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

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

Clinical Evidence

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

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.

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.

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 randomized controlled trials, 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 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 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.

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). These findings are limited by lack of concurrent comparison group undergoing a different therapeutic approach.

Yuan et al. (2010) conducted a prospective, RCT of HFCWC in pediatric patients with NMD and cerebral palsy (CP). Twenty-three patients (nine 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 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).

Intrapulmonary Percussive Ventilation (IPV)

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

Nicolini et al. (2018) conducted a four-week randomized control trial to determine if adding Intrapulmonary percussive ventilation (IPV) or high-frequency chest wall oscillation (HFCWO) with the best pharmacological therapy (PT) will provide clinical benefit to Chronic Obstructive Pulmonary Disease (COPD) patients over just chest physiotherapy (CPT). There was a total of 63 patients randomized into three groups (20 patients completed the trial in each group): IPV group (treated with PT and IPV), PT group with (treated with PT and HFCWO), and control group (treated with PT alone). Primary outcomes measured are the dyspnea scale (modified Medical Research Council [mMRC]) and Breathlessness, Cough, and Sputum scale (BCSS), along with daily life activity (COPD Assessment Test [CAT]). Secondary outcomes measured are pulmonary function testing (PFT), arterial blood gas analysis, and hematological examinations. Patients in both the IPV and HFCWO group showed marked improvement in dyspnea and mMRC, BCSS and CAT compared to the control group. IPV patients showed an improvement in BCSS ($p = 0.001$) and CAT ($p = 0.02$) scores in comparison with HFCWO. Both IPV and HFCWO secondary outcomes improved compared to the control group. In the group comparison analysis of the IPV group and HFCWO group variables, there was marked improvement in the IPV group in total lung capacity (TLC) and TLC% ($p = 0.03$), residual volume (RV) and RV% ($p = 0.04$), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal lung capacity (MEP) ($p = 0.01$). Limitations of this study included single center, small sample size and short duration. The authors concluded that both IPV and HFCWO can improve lung function, muscular strength, dyspnea, and overall health status. and that IPV demonstrated better effectiveness in improving test results in small bronchial airways and alveolar ventilation (RV and DLCO) and muscular strength (MIP and MEP) as well as scores on daily life activity and health status assessment scales (BCSS and CAT) compared with HFCWO. A multi-center, larger population, and measurement of primary and secondary outcomes over a longer term are needed. Limitations of this study included single center, small sample size and, short duration and lack of masking or sham procedure. Furthermore, the intervention was delivered by a physical therapist; therefore, these findings may not be generalizable to IPV used at home and without professional supervision or for conditions other than COPD.

Reychler et al. (2018) conducted a systematic review to summarize the physiological and clinical effects related to the use of intrapulmonary percussive ventilation (IPV) as an airway clearance technique in chronic obstructive airway diseases. Using predetermined criteria, a search was conducted in PubMed, PEDro, and Scopus online databases. Outcomes of interest included immediate or prolonged physiological effects (e.g., gas exchange, cardiorespiratory parameters, lung function, and mechanics) and clinical effects (e.g., symptoms, adverse effects, and length of hospital stay). A total of 109 studies were identified and after further evaluation, 12 studies were included in the review. Of those, one study evaluated patients with bronchiectasis ($n = 22$), four studies evaluated patients with cystic fibrosis ($n = 78$), and six studies (1 study included phase 1 and 2 results) evaluated patients with chronic obstructive pulmonary disease (COPD, $n = 178$). In patients with COPD, IPV improved gas exchange during exacerbation and reduced the hospital length of stay however, IPV was no more beneficial than other airway clearance techniques when subjects were stable. Two studies reported complications or discomfort with IPV and in another study, two patients did not tolerate settings with a higher frequency of percussions (1.220 cm H₂O-350 c/min and 1.840 cm H₂O-350 c/min). In patients with cystic fibrosis, cardiorespiratory parameters and lung function did not improve with

IPV. One study reported mild hemoptysis, which was associated with a respiratory infection. In patients with bronchiectasis, dyspnea and respiratory frequency improved after one session of IPV however, there was no difference in sputum dry weight and in patients with productive bronchiectasis, immediate efficacy of IPV vs. other airway clearance techniques did not differ. Minor adverse events (dry throat, nausea, and/or fatigue) were reported in 27% of patients treated with both IVP and chest physical therapy. The authors concluded that use of IPV as an airway clearance technique in chronic obstructive airway diseases is not supported by sufficiently strong evidence to recommend routine use in this patient population.

Clinical Practice Guidelines

American Academy of Neurology (AAN)

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

American 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

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 July 30, 2021)

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
06/01/2022	Coverage Rationale <ul style="list-style-type: none">Removed reference to specific InterQual® release date; refer to the most current InterQual® criteria Supporting Information <ul style="list-style-type: none">Archived previous policy version CS054NE.O

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.