High Frequency Chest Wall Compression (e.g. The Vest Airway Clearance System)

Policy MP-031

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Respiratory disorders characterized by excessive respiratory secretions and impaired airway clearance include cystic fibrosis, chronic bronchitis, emphysema with a chronic bronchitic component, chronic asthma, dyskinetic cilia syndromes, diffuse panbronchiolitis, and idiopathic bronchiectasis. Neuromuscular diseases, such as muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS) can also result in the inability of the patient to effectively clear mucus from the airways.

When conventional postural drainage therapy and other devices have failed or are contraindicated, high-frequency chest wall compression (HFCWC) is often considered as a treatment option for patients with disease that cause difficulty clearing secretions. HFCWC, a mechanical form of chest physiotherapy, is a system composed of a fitted vest coupled to a pneumatic compressor that uses high frequency oscillation to provide chest physiotherapy. The compressor inflates and deflates the vest, compressing and releasing the chest wall to create airflow within the lungs. The vibrations, along with the increase in airflow, help loosen mucus from the lungs. Children as young as three years of age are able to use the vest.

HFCWC is an established airway clearance device for patients with cystic fibrosis who cannot tolerate chest physiotherapy or in whom chest physiotherapy has been shown to be ineffective or is contraindicated.

HFCWC (high-frequency chest wall compression devices) (e.g. the Vest™ Airway Clearance System, formerly known as the ABI Vest® or the ThAIRapy Bronchial Drainage System®) are passive oscillatory devices designed to provide airway clearance without the active participation of the patient. The Vest™ Airway Clearance System provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator creates pressure pulses that cause the vest to inflate and deflate against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers high frequency chest wall compression therapy in limited clinical circumstances.

Medical Necessity Criteria for Coverage of HFCWC Therapy (Must Meet A-D):

A. Member has one of the following conditions:

   i. Cystic fibrosis;

   ii. Chronic diffuse bronchiectasis, which is defined by a daily productive cough for at least 6 continuous months, or more than 2 times a year exacerbations requiring antibiotic therapy, and confirmed by high resolution or spiral chest computed tomography scan;

   iii. Chronic neuromuscular disease with respiratory muscle weakness affecting the ability to cough or clear respiratory secretions with prior history of pneumonia or other significant worsening of pulmonary function;

   iv. Immotile Ciliary Dysfunction/Primary Ciliary Dyskinesia.

B. There is documentation of either failure of or inability to use other airway clearance therapies including manual chest physical therapy due to any one of the following:

   i. There are 2 or more individuals with cystic fibrosis, chronic bronchiectasis, or chronic neuromuscular disorder (meeting criteria above) in the family

   ii. The caregiver is unable (physically or mentally) to perform chest physical therapy at the required frequency

   iii. There is no available caregiver, parental or partner resource to perform chest physical therapy

   iv. Well-documented failure of standard treatments to adequately mobilize retained secretions, with ALL the following (a-c):

      a. Failed Chest PT at least twice daily; and

b. A pattern of hospitalizations or significantly deteriorating clinical condition; and
c. Adequate cough to remove mobilized secretions or use of cough assist device.

C. There is documentation of an initial 60 day trial during which at least an 80% compliance with the device has been demonstrated AND the patient has documentation of improved ventilator function; and

D. The device is prescribed by a pulmonary specialist.

U of U Health Plans considers continued use of a high frequency chest compression device is medically necessary when ongoing use, (that is, compliance with use) is documented at 6 month to 12 month intervals. (Note: For high frequency chest compression devices with usage meters, documentation should reflect use, in general, at least 80% of the prescribed time).

U of U Health Plans considers high frequency chest compressions NOT medically necessary if the above criteria are not met.

U of U Health Plans considers high chest wall frequency chest compression not medically necessary for all other indications, including but not limited to, chronic obstructive pulmonary disease (COPD), Cerebral Palsy and individuals with known cardiac conditions.

2. **Medicaid Plans**

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

The evidence from 3 Cochrane systematic reviews (Morrison et al., 2014, McIlwaine et al., 2015 and Mckoy et al., 2016) also found a low level of evidence for the use of HFCWC in patients with CF. However, further studies are needed.

The evidence for use of these vests in neuromuscular disease is limited. The studies tend to be small without randomization. There are 2 studies, a 2016 retrospective review (Lechtzin et al.) and a 2022 prospective cost analysis (Ansaripour et al.), both of which suggest cost is less due to decreased hospitalization. The majority of clinics that deal with these patients feel that by the time HFCWC is initiated, randomized trials are no longer ethical due to the precarious nature of their disease.

A prospective, RCT of high-frequency chest wall oscillation (HFCWC) in 23 pediatric patients 14 with NMD and 9 cerebral palsy (CP) (Yuan et al., 2010). 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 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 heterogeneous nature of diagnoses and short-term follow-up.

In 2014, a single-center, prospective study (Fitzgerald et al.) evaluated the clinical feasibility of HFCWC therapy in neurologically impaired children with respiratory symptoms. Twenty Two 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 found that regular HFCWC therapy may reduce the number of hospitalizations in neurologically impaired children. However, these findings are limited by lack of concurrent comparison group undergoing a different therapeutic approach.

A 2016 cohort study (Lechtzin et al.) analyzed healthcare claims before and after initiation of HFCWC to compare whether this modality led 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 HFCWC 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. In conclusion, the total medical costs, hospitalizations, and pneumonia claims were less after initiation of HFCWC in a broad group of patients with NMD. Limitations of the study included administrative data that did not capture how HFCWC was used and that HFCWC may be a marker of generally better care in the routine use of this intervention in the care of patients with NMD. Also, findings are limited by lack of concurrent comparison group undergoing a different therapeutic approach.

In 2019 ECRI identified and reviewed 1 international single-blind RCT (n=73), 1 international open label RCT (n=50), and 1 prospective case series (n=25) conducted in the U.S. in a custom product brief on The Vest Airway Clearance System®. 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. In conclusion, to better help providers in making informed decisions on how well HFCWC with the Vest system works relative to other mechanical or intrapulmonary flow percussion devices, more robust, multicenter blinded RCTs are needed.

Lastly, in 2022 Anasaripour et al. investigated the budget impact of HFCWO versus chest wall physical therapy (CWPT) in patients with complex neuromuscular disorders (cNMD) from a U.S. commercial payer perspective. In combination with a previously developed cost-effectiveness model, a budget impact model was developed to evaluate the incremental budgetary impact associated with introducing a HFCWO device over a 5-year time horizon. In a hypothetical plan of 1,000,000 members (men: 49.2%), 2099 patients with cNMD were estimated to be eligible to receive airway clearance services over 5 years. The new scenario (HFCWO and CWPT [US$24 PMPY]) was cost-saving compared with the current scenario (CWPT only [$34 PMPY]) with a cost reduction of US$9.46 PMPY. The model estimated a net cost-saving of US$1,594,131 and US$9,591,343 over 1 and 5 years, respectively. The authors found that this study suggests the HFCWO technique to manage the reduction in vital capacity in patients with cNMD would lead to favorable budget impact results.

American Academy of Neurology (AAN) (Miller et al., 2009; reaffirmed 2020) in their practice parameters on the care of patients with amyotrophic lateral sclerosis (ALS), concluded that high frequency chest wall compression (HFCWC) is unproven for adjunctive airway secretion management.

National Institute for Health and Clinical Excellence (NICE): In a guidance for the management of cystic fibrosis, NICE (2017, updated 2022) stated that HFCWC should not be offered as an airway clearance technique for people with cystic fibrosis except in exceptional clinical circumstances because the evidence has shown that high-frequency chest wall oscillation is not as effective as other airway clearance techniques. Airway clearance techniques for these patients should be individualized based on the patients' ability to clear mucus from their lungs, and all factors that may influence adherence should be considered. The effectiveness of the technique should be assessed frequently and modified as needed.

In a consensus statement on the respiratory care of patients with Duchenne muscular dystrophy (DMD), the American Thoracic Society (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 recommended 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.

Data is extremely limited for disorders such as COPD and does not support the use of this vest with these types of disorders.

Applicable Coding

CPT Codes

No applicable CPT codes

HCPCS Codes

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, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each

ICD-10 Codes:

A15.0	Tuberculosis of lung (tuberculous bronchiectasis)
E84.0-E84.9	Cystic Fibrosis
G12.0-G12.9	Spinal muscular atrophy and related syndromes
G24.9	Dystonia, unspecified
G35	Multiple sclerosis
G71.2	Congenital myopathies
G71.11-G71.19	Myotonic disorders
G72.0-G72.9	Other and unspecified myopathies
J47.0-J47.9	Bronchiectasis
G82.20-G82.54	Paraplegia (paraparesis) and quadriplegia (quadriparesis) [regardless of underlying etiology]
J98.09	Other diseases of bronchus, not elsewhere classified
J98.6	Disorders of diaphragm (paralysis of the diaphragm)
Q33.4	Congenital bronchiectasis
Q34.8	Other specified congenital malformations of respiratory system
Q89.3	Situs inversus

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