



Clinical Review Criteria

High-Frequency Chest Wall Oscillation Devices (HFCWO)

- ABI Vest® for Cystic Fibrosis
- Vest™ Airway Clearance System

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	High Frequency Chest Wall Oscillation Devices (L33785)

For Non-Medicare Members

- A. The member must have **ONE of the following**:
1. A diagnosis of cystic fibrosis.
 2. A diagnosis of bronchiectasis:
 - a) Characterized by daily productive cough for at least 6 continuous, months or, frequent (i.e. more than 2/year) exacerbations requiring antibiotic therapy, and
 - b) Confirmed by high resolution, spiral, or standard CT scan
 3. Neuromuscular Disorder
 - a) Acid maltase deficiency
 - b) Anterior horn cell diseases, including amyotrophic lateral sclerosis
 - c) Hereditary muscular dystrophy
 - d) Multiple sclerosis
 - e) Myotonic disorders
 - f) Other myopathies
 - g) Paralysis of the diaphragm
 - h) Post-polio
 - i) Quadriplegia regardless of underlying etiology.
- B. And meet **ALL of the following** criteria:
1. Well-documented failure of standard treatments to adequately mobilize retained secretions with all of the following:
 - a) Chest physical therapy and flutter device at least twice daily (when age appropriate)
 - b) A pattern of hospitalizations at least annually or more
 - c) Significantly deteriorating clinical condition
 2. Be under the care of a pulmonologist
 3. Had a rental trial to confirm compliance before purchase

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Conventional chest physical therapy (CPT), also known as percussion and postural drainage (P/PD) has traditionally been the standard of care of secretion clearance methods for patients with excessive or retained lung secretions. Depending on the severity of the disease or the presence of infection, CPT is performed in 1-3

sessions per day, each lasting between 23-30 minutes. These are administered by a physical therapist or a trained caregiver. CPT is labor intensive and time consuming, which could lead to poor compliance.

A number of airway clearing devices have thus been developed for independent use with little or no assistance by others. These include the high-frequency chest wall oscillation (HFCWO), which is an external non-invasive respiratory modality that mobilizes airway secretions from the small peripheral airways. The technique typically produces compression of the chest wall via an inflatable vest linked to an air pulse generator. The generator delivers an intermittent flow to the vest which rapidly compresses and releases the chest wall at a variety of frequencies. Consequently, an oscillation of airflow within the airways is achieved. The researchers believe that the underlying mechanisms include increased airflow-mucous interaction causing a reduction in viscoelasticity, production of airflow bias that promotes a cephalad movement of the mucous, as well as the enhancement and stimulation of ciliary activity (Osman 2010).

HFCWO is most commonly used for assisting mucous secretion in patients with disorders associated with abnormally thick mucous hypersecretion but preserved muscle function such as cystic fibrosis. It has also been advocated as an adjunctive therapy to assist cough clearance in patients with neuromuscular disorders who have relatively normal mucus but weak respiratory muscles (Chaisson 2006, Osman 2010, Finder 2010).

The FDA has cleared several airway clearing systems for delivering high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage in situations where physicians recommend external manipulation of the thorax. These systems include the Vest™ Airway Clearance System (also known as the ABI Vest or the ThAIRapy Vest, or the ThAIRapy Bronchial Drainage System), Medpulse Respiratory Vest System, and the FREQUENCER which produces sound wave stimulation to oscillate and loosen mucous secretion in the chest.

HFCWO is most commonly used with cystic fibrosis patients who have abnormally thick secretions. It has also been used for other conditions such as bronchiectasis. Another proposed application is treating patients with neuromuscular disorders, who may have impaired cough and may not be able to clear their airways. An inadequate cough in these patients can lead to atelectasis or pneumonia. Other possible treatments for airway clearance in patients with neuromuscular disorders include percussion and postural drainage (P&PD), the traditional procedure, autogenic drainage, positive expiratory pressure therapy, flutter valve and intrapulmonary percussive ventilation (IPV) (Panitch et al., 2006; Langenderfer, 1998).

Neuromuscular diseases are a heterogeneous group of inherited or acquired disorders characterized by progressive irreversible weakness of functional groups of skeletal muscles including the respiratory muscles necessary for ventilation and cough. Depending on the severity of the disorder, ineffective cough and clearing of respiratory secretions can present as frequent respiratory infections, pneumonias, and atelectasis. As the disorder progresses, the patients may develop spinal deformities, gas exchange abnormalities, sleep disorders, and cardiac dysfunction. These and any concomitant pulmonary disorder can severely compromise the existent muscle weakness and precipitate respiratory failure (Chaisson 2006, Yuan 2010).

The Vest™ Airway Clearance System (Hill-Rom, ST Paul, Minnesota), consists of a 1. Non-stretching inflatable cloth-like vest that covers the entire thorax and provides high frequency chest wall oscillation; 2. Large-bore tubing connects the vest to the air-pulse generator; and 3. An air pulse generator that creates pressure to inflate and deflate the vest against the thorax. The vest is inflated to a constant pressure to maximize the surface area over which high frequency (5-20 Hertz), small volume pressure impulses are transmitted externally to the entire chest area. Pressure pulses are controlled by the patient and applied during expiration. A typical treatment may last for 20-30 minutes, and consists of periods of compression separated by huff coughs (Chatburn 2007).

Medical Technology Assessment Committee (MTAC)

ThAIRapy/ABI Vest

12/13/2000: MTAC REVIEW

Evidence Conclusion: The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI Vest® on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI Vest® compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluff study included only 29 individuals, had a brief intervention (4 days total), no “wash-out” period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time

series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI Vest®.

Articles: The search yielded 20 articles. 11 articles were not directly relevant or were review articles. Of the remaining 9 articles, 5 were randomized controlled trials (RCTs). The two RCTs with the largest sample sizes were selected for critical appraisal (the remaining three RCTs all had sample sizes of less than 20 patients). In addition, an interrupted time-series analysis with longer-term follow-up of patients was reviewed. Arens R, Gozal D, Omlin KJ, Vega J, Boyd KP, Keens TG, Woo MS. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. *Am J Respir Crit Care Med* 1994; 150: 1154-7. See [Evidence Table](#). Kluff J, Beker L, Castagininio M, Gaiser J, Chaney H, Fink RJ. A comparison of bronchial drainage treatments in cystic fibrosis. *Pediatr Pulmonol* 1996; 22: 271-74. See [Evidence Table](#). Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. *Pediatr Pulmonol* 1991; 11: 265-71. See [Evidence Table](#).

The use of ThAIRapy/ABI Vest® for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

ThAIRapy/ABV Vestâ

10/08/2003: MTAC REVIEW

Evidence Conclusion: There is no published empirical evidence on the use of the Vest™ Airway Clearance System for bronchiectasis. There is no new published evidence on the use of the Vest™ Airway Clearance System for cystic fibrosis. The summary of the evidence on the ABI vest from December, 2000 is: "The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI vest on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI vest compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluff study included only 29 individuals, had a brief intervention (4 days total), no "wash-out" period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI vest."

Articles: The search yielded 6 articles. There were no new empirical studies on the Vest™ Airway Clearance System for cystic fibrosis. There were no empirical studies on the Vest™ Airway Clearance System for bronchiectasis.

The use of ThAIRapy/ABI Vestâ for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

High Frequency Chest Wall Oscillation

02/04/2008: MTAC REVIEW

Evidence Conclusion: There is no empirical evidence on the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in patients with neuromuscular disease.

Articles: The search yielded 11 articles. When limited to English language publications and human populations, there were 7 articles. Only 2 of the 7 articles, both of them reviews/opinion pieces, specifically addressed the topic of interest, airway clearance for patients with neuromuscular weakness. The remaining articles were on different, related topics. No empirical studies were identified. One of the review articles (Panitch, 2006) stated that HFCWO has not been studied in patients with neuromuscular disease.

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/18/2010: MTAC REVIEW

High Frequency Chest Wall Oscillation

Evidence Conclusion: The evidence on the use of high-frequency chest wall oscillation (HFCWO) therapy in patients with neuromuscular disorders is very limited and insufficient to determine the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in these patients. The published studies to date have very small sample sizes and short follow-up durations. Those with a control group have several threats

to their internal validity. Among these are unblinding, including heterogeneous groups of population, potential selection bias, insufficient power to detect significant differences between therapies, relatively high dropout rates, and/or analyses were not based on intention to treat. Additionally the studies were funded by the manufacturer of the airway clearance systems used.

Articles: The majority of published literature on high-frequency chest wall oscillation (HFCWO) was on its use for patients with cystic fibrosis and other obstructive airway diseases. The literature search for studies published after the last MTAC review of the technology for patients with neuromuscular disorders revealed only one small RCT that compared the use of HFCWO to the standard chest physiotherapy among a small group of pediatric population with cerebral palsy or neuromuscular disease. Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. *J Child Neurol.* 2010;25:815-821. See [Evidence Table](#)

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Dates Reviewed	Date Last Revised
12/13/2000	12/07/2010 ^{MDCRPC} , 02/10/2011 ^{MDCRPC} , 12/06/2011 ^{MDCRPC} , 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/03/2014 ^{MPC} , 04/07/2015 ^{MPC} , 02/02/2016 ^{MPC} , 12/06/2016 ^{MPC} , 10/03/2017 ^{MPC} , 08/07/2018 ^{MPC}	10/08/2009

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
01/19/2016	Defined conditions for neuromuscular disorder

Codes

HCPCS: A7025, A7026, E0483, E0480