CLINICAL MEDICAL POLICY and PRIOR-AUTHORIZATION POLICY	
Policy Name:	Passive Oscillatory Devices in the Outpatient Setting
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Approved By:	Medical Management
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Application:	All participating hospitals and providers
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Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

*All medical policies are available on the Gateway provider website at:

http://gatewayhealthplan.com/MedicalPolicies

POLICY STATEMENT:

Gateway Health℠ provides coverage under the Durable Medical Equipment (DME) benefits of the Company's Medicaid products for medically necessary passive oscillatory/high-frequency chest wall oscillation devices.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records.

(Current applicable PA HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS:

Prior Authorization Review Panel – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Bronchiectasis - A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or a congenital condition.

Bronchitis - An inflammation of the upper airways, associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last 2 or more years, a person has been coughing up some mucus every day, for at least 3 months out of the year.

Chest physiotherapy (CPT) (also known as chest physical therapy) - CPT traditionally has meant the use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is to improve mucociliary clearance and pulmonary function, in order to reduce the risk of infection and lung damage.

Cystic fibrosis (CF) - An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF.

High-frequency chest compression (HFCC) - A treatment designed to help improve secretion clearance for individuals suffering from excessive or retained lung secretions. Currently, several conventional therapies, such as percussion on the thorax and postural drainage (P/PD), are used to produce this effect, particularly in cystic fibrosis (CF). These individuals have difficulty clearing lung secretions which leads to difficulty in breathing, infection, hypoxemia, and bronchiectasis.

High-frequency chest wall oscillation (HFCWO) - The mechanized technology employed by HFCC. HFCWO involves air pulses generated at various frequencies that are transmitted through a vest and compress the user's chest.

Vest Airway Clearance System (also known as the ABI Vest, ThAIRapy Vest, or the ThAIRapy Bronchial Drainage System® - HFCC devices that consist of an air generator and an inflatable vest that covers the thorax and provides high frequency chest wall oscillation. Large-bore tubing connects the vest to the air-pulse generator which 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. The device is designed for self-therapy and consists of a large volume, variable frequency, air pulse delivery system and a non-stretchable inflatable vest worn by the user. Pressure pulses are controlled by the user and applied during expiration. This device has 510(k) clearance status with the FDA.

Postural Drainage – Drainage of the lungs by placing the patient in an inverted position so that fluids are drawn by gravity toward the trachea.

Vibratory/oscillatory positive expiratory pressure (PEP) devices (FLUTTER®, Acapella®) - With PEP devices the patient exhales multiple times through a device. The FLUTTER device is a small pipe-shaped, easily portable hand-held device, with a mouthpiece at one end. It contains a high-density stainless steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs,

resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create air flow oscillation.

PROCEDURES

This policy addresses the use of oscillatory devices in the outpatient setting only. Use of this device during an inpatient admission is not included in the policy.

1. Initial use of a high frequency chest compression (HFCC) device is covered when the following medical necessity criteria are met:
    a. The device is cleared by the FDA; and
    b. There is documented need for airway clearance; and
    c. The individual has one of the following diagnoses and documented in the medical record:
        i. Cystic fibrosis (CF); OR
        ii. Chronic bronchiectasis-as defined by daily productive cough for at least 6 continuous months, or more than two exacerbations per year, requiring antibiotic therapy and confirmed by high resolution or spiral chest CT scan; OR
        iii. Chronic neuromuscular disorder affecting the ability to cough or clear respiratory secretions with prior history of pneumonia or other significant worsening of pulmonary function. (Chronic neuromuscular disorders such as: hereditary muscular dystrophy, multiple sclerosis, myotonic disorders, post- polio, quadriplegia regardless of underlying etiology, anterior horn cell diseases-including amyotrophic lateral sclerosis, myasthenia gravis, & acid maltase deficiency)
    d. There should be demonstrated presence of bronchopulmonary secretions with need for airway clearance. The device should not be used prophylactically to prevent onset of respiratory symptoms; AND
    e. Conventional manual chest PT (CPT) is unavailable, ineffective, or not tolerated as age appropriate. There should be documented failure of standard treatments (chest physiotherapy and, if appropriate use of an oscillatory positive expiratory pressure device such as Flutter Device® or Acapella®), or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it. Valid reasons would include but are not limited to: physical or emotional disability, time limitations. Severity of the pulmonary disease requires complex or frequent therapy, an independent individual without parents or capable partner, or a rehabilitation plan that includes promotion of independent, self-administered, easily supervised therapy; AND
    f. A trial period is required to determine patient and/or family compliance. Sufficient and appropriate usage of the device during the trial period must be documented. There is evidence that the member utilizes the therapy at least twenty minutes per day. Note: For high frequency chest compression devices with usage meters, documentation should reflect use, in general, at least 67% of the time; AND
    g. The device is prescribed by either a pulmonologist or a cystic fibrosis clinic.

2. Flutter ® Device
   The Flutter® valve and Acapella® are considered medically necessary when used on a daily basis for patients with hypersecretory lung disorders and when the patients are required to do daily pulmonary drainage or compression physiotherapy to help loosen secretions from the respiratory tract.

   The patient must be diagnosed with one of the following conditions:
   - Bronchiectasis
   - Ciliary dyskinesia
   - Ciliary fibrosis
   - Cystic fibrosis

4. Contraindications
   Contraindications exist for external manipulation of the thorax, as outlined by the American Association of Respiratory Care (AARC) and contained in their clinical practice guidelines for Postural Drainage Therapy, which include, but may not be limited to: unstable head or neck injury; active hemorrhage with hemodynamic instability; subcutaneous emphysema; recent epidural, spinal fusion or spinal anesthesia; recent skin grafts or flaps on the thorax; burns, open wounds, and skin infections of the thorax; recently placed transvenous pacemaker or subcutaneous pacemaker; suspected pulmonary tuberculosis; lung contusion; bronchospasm; osteomyelitis of the ribs; osteoporosis; coagulopathy; and complaint of significant chest wall pain.

5. When passive oscillatory devices are not covered
   For conditions other than those listed above scientific evidence has not been established and will be denied as not medically necessary.

   Intrapulmonary percussive ventilatory (IPV) devices are considered experimental/investigation and not medically necessary as there is not sufficient scientific evidence demonstrating a positive impact on health outcomes.

   There are limited studies evaluating oscillatory devices for the treatment of acute exacerbations and chronic COPD, and other respiratory conditions. The available scientific evidence did not find that these devices were more effective than conventional treatment. Therefore, use of high frequency chest wall compression for all other conditions is considered **not medically necessary.**

   Use of the passive oscillatory device in persons with chronic bronchitis or COPD in the absence of a confirmed diagnosis of bronchiectasis is not medically necessary.

6. DME
   The passive oscillatory device (E0483) is classified as a DME rental item and may be subject to prior authorization requirements.

   Continued use of a HFCC device is considered **medically necessary** when ongoing use, (compliance with use) is documented at monthly intervals. (Note: For HFCC devices with usage meters, documentation should reflect use, in general, at least 67% of the prescribed time.)

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

8. Place of Service
   For purposes of this medical policy, the place of service is in the home setting.

9. Governing Bodies Approval
   Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process including the following:
   - The Bird IPV Noncontinuous Ventilator (Percussionaire Corp) in 1989

- Flutter® Mucus Clearance Device in 1994. The Flutter device is currently marketed in the United States by Axcan.
- The ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by the FDA—most recently a fifth generation device. The device is now known as the Vest™ Airway Clearance System and it is manufactured by Hill-Rom.
- The Acapella® device (DHD Healthcare) in 1999
- The RC Cornet™ Mucus Clearing Device (PARI Respiratory Equipment) in 1999
- The inCourage® System (Respiratory Technologies; Lakeville, MN) in 2005
- The Vibralung Acoustical Percussor (Westmed Inc., Tucson, AZ) in May 2014

A similar device, the MedPulse Respiratory Vest System (Electromed, Inc., Minnetonka, MN) also obtained FDA clearance through the 510(k) approval process (1999), and others have also been cleared by the FDA. In 2007, a similar device, the Frequencer™ (DYMEDSO, Inc., Boisbriand, Quebec Canada) obtained FDA clearance as substantially equivalent to the ThAIRapy device. It produces sound wave stimulation to oscillate and loosen mucous secretions in the chest.

Other names used to report oscillatory/high frequency devices:
- ABI Vest
- Acapella® device (DHD Healthcare)
- Bird IPV® Noncontinuous Ventilator (Percussionaire Corp)
- Flutter® Mucus Clearance Device (Axcan)
- Frequencer
- High frequency chest compression (HFCC)
- High frequency chest wall oscillation (HFCWO)
- InCourage Vest/System
- Intrapulmonary Percussive Ventilation (IPV)
- Intrapulmonary percussive ventilatory
- MedPulse Respiratory Vest System
- Oscillatory devices
- Percussionaire
- RC Cornet™ Mucus Clearing Device (PARI Respiratory Equipment)
- Respin11 Bronchial Clearance System (MedInnovation/RespInnovation)
- SmartVest
- ThAIRapy Vest System®
- Vest™ Airway System

The ThAIRapy Bronchial Drainage System. Since 1998, updated versions of the device were cleared by the FDA—most recently a fifth generation device. The device is now known as the Vest™ Airway Clearance System, and it is manufactured by Hill-Rom.

CODING

Procedure Codes

HCPCS Codes	Description
E0483	High frequency chest wall oscillation air-pulse generator system, including hoses and vest, each
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
S8185	Flutter® Device

Diagnosis Codes

ICD 10 Diagnosis Codes	Description
A15.0	Tuberculous bronchiectasis
A80.39	Other acute paralytic poliomyelitis
E74.00	Glycogen storage disease, unspecified
E74.01	Von Gierke's disease
E74.04	McArdle's disease
E74.09	Other glycogen storage disease
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis unspecified (without meconium ileus)
G12.22	Progressive bulbar palsy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G35	Multiple sclerosis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G70.1	Toxic myoneural disorders
G70.2	Congenital and developmental myasthenia
G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G70.89	Other specified myoneural disorders
G70.9	Myoneural disorder, unspecified
G71.0	Muscular dystrophy
G71.11	Myotonic muscular dystrophy
G71.12	Motonia congenita
G71.13	Myotonic chondrodystrophy

G71.14	Drug induced myotonia
G71.19	Other specified myotonic disorders
G71.2	Congenital myopathies
G73.1	Lambert-Eaton syndrome in neoplastic disease
G73.3	Myasthenic syndromes in other disease classified elsewhere
G80.0	Spastic quadriplegic cerebral palsy
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G85.54	Quadriplegia, C5-C7 incomplete
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
J98.6	Disorders of the diaphragm
R53.2	Functional quadriplegia
Q33.4	Congenital bronchiectasis

Summary of Literature

A passive oscillatory device is used to promote airway clearance or improve bronchial drainage by enhancing mobilization of bronchial secretions, where external manipulation of the thorax is the physician's choice of treatment. The indications typically follow the Clinical Practice Guideline published by the American Association for Respiratory Care (AARC) in 1991. In addition, the device is also indicated for the purpose of collecting mucus for diagnostic evaluation.
The American College of Chest Physicians' evidence-based clinical practice guidelines on non-pharmacologic airway clearance therapies (McCool and Rosen, 2006) recommend oscillatory devices (e.g., Flutter, IPV, and HFCWO) be considered as an alternative to chest physiotherapy only in CF patients.

The Flutter® is an oscillating positive expiratory pressure (PEP) device that requires active participation by the patient. It is a small pipe-shaped hand held device that is portable. There is a high-density steel ball that lays in a plastic circular cone. Upon patient exhalation, the steel ball moves up and down creating oscillations in the expiratory pressure and airflow. When the oscillation frequency nears the resonance frequency of the pulmonary system, there is airway vibration that results in loosening of mucous. While the Acapella device is similar, it uses a counterweight plug and magnet to create air flow oscillation.

McIlwaine et al (2013) published a random controlled trial that compared two types of oscillatory devices, the positive expiratory pressure (PEP) device using a face mask and the high frequency chest wall oscillation device. The one year study included patients that were older than 6 years of age with clinically stable CF; ages ranged from 6 to 47 with random assignment of the two devices. Eighty-eight (82%) of the 107 randomized patients completed the study. At study end, there were 49 exacerbations requiring antibiotics in the PEP group with 96 in the high frequency chest wall oscillation group. The difference between the two groups was statistically significance favoring the PEP device. Limitations of the study include patients not being blinded in the study and that there was a nearly 20% dropout rate. Eight patients in each arm of the study dropped out after randomization and another three patients dropped out during the intervention phase.

Yuan and colleagues (2010) stated that airway secretions and infections are common in cerebral palsy (CP) and neuromuscular diseases. Chest physiotherapy is standard therapy but effort is substantial. High-frequency chest wall oscillation (HFCWO) is used in CF, but tolerability and safety data in cerebral palsy and neuromuscular disease are limited. These researchers performed a prospective, randomized, controlled trial of HFCWO and standard CPT in patients with neuromuscular disease or CP. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, chest radiographs, and polysomnography. Caregivers were questioned regarding therapy adherence. A total of 28 participants enrolled and 23 completed the study (12 CPT, mean study period 5 months). No adverse outcomes were reported. Adherence to prescribed regimen was higher with HFCWO ($p = 0.036$). These findings suggest safety, tolerability, and better compliance with HFCWO. Improvement in airway clearance may help prevent hospitalizations. The authors noted that larger controlled trials are needed to confirm these results.

In 2011, Chakrovorty et al. reported on a study evaluating high frequency chest wall compression devices in patients with moderate to severe COPD and mucus hypersecretion. A total of 30 patients enrolled in the study and 22 completed the four week trial. Eight patients withdrew due to COPD exacerbations, eleven patients started with the device and changed to conventional treatment. The remaining eleven patients started with conventional treatment and crossed over the device. While the primary outcome of the study was quality of life, the secondary outcome measured was FEV1 or FVC improvements. The authors reported there were no significant differences in the secondary outcomes.

In another study reported by Goktalay et al. (2013), a total of 50 hospitalized patients with stage 3-4 COPD were randomized into receiving 5 days of medical treatment with high frequency chest wall compression therapy (25) or medical therapy alone (25). Outcome measurements including FEV1, MMRC dyspnea scores and the 6 minute walk failed to demonstrate significant differences.

Intrapulmonary percussive ventilation (IPV) is a technique which utilizes high frequency oscillatory ventilation to produce endotracheal percussion via a device called the percussionator. This device (E0481) is an adaption of a pneumatic high frequency ventilator where high flow jets of gas are delivered to the airways by a flow interrupter called a phasitron. An IPV delivers a series of pressurized gas mini-bursts at rates greater than 100 cycles per minute to the respiratory tract.

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