CLINICAL MEDICAL POLICY	
Policy Name:	Passive Oscillatory Devices in the Outpatient Setting
Policy Number:	MP-029-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	02/01/2024; 12/01/2022; 12/17/2021; 12/21/2020; 01/20/2020; 01/15/2019; 02/15/2018; 12/01/2016
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Next Annual Review:	10/2024
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 11

Policy History

Date	Activity
02/01/2024	Provider Effective date
01/04/2024	PARP Approval
10/18/2023	QI/UM Committee review
10/18/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
01/01/2023	Provider Effective date
11/08/2022	PARP Approval
10/19/2022	QI/UM Committee review
10/19/2022	Annual Review: No changes to clinical criteria. Revised 'Procedure' section wording. Updated 'Summary of Literature' and 'Reference Sources' sections. Corrected code description for the following ICD-10 codes: A15.0, E84.9, G12.20, & M35.03.
01/17/2022	Provider effective date
11/30/2021	PARP approval
10/20/2021	QI/UM Committee review
10/20/2021	Annual Review: No changes to clinical criteria. Added 'Primary ciliary dyskinesia' definition. Made minor formatting changes to the 'Procedures' section. Removed diagnosis code G71.2; added the following diagnosis codes: G71.21 G71.220,

	G71.228, and G71.29 according to AMA coding guidelines. Updated the Summary of Literature and Reference Sources sections.
01/18/2021	Provider effective date
12/02/2020	PARP approval
10/21/2020	QI/UM Committee review
10/21/2020	Annual Review: No clinical criteria changes, updated Summary of Literature and References section.
01/20/2020	Provider Effective Date
11/25/2019	PARP approval
10/16/2019	QI/UM Committee Review
10/16/2019	Annual Review: No clinical criteria changes; formatting changes; revised description for E0483; deleted ICD-10 codes A80.39 and E84.11 as inappropriate for the policy; Added ICD-10 codes G12.1, G71.2, M33.02, M33.12, M33.22, M99.92, M34.82 and M35.03 as eligible; updated references.
01/15/2019	Provider effective date

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare provides coverage under the Durable Medical Equipment (DME) benefit 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 warrant 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 (PARP) – A panel of representatives from within the PA 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 bronchial 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. . The purpose of CPT is to improve mucociliary clearance and pulmonary function, in order to reduce the risk of infection and lung damage. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia

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. These individuals have difficulty clearing lung secretions which leads to difficulty in breathing, infection, hypoxemia, and bronchiectasis. 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).

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. 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. 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. 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, the patient who exhales multiple times through a device. PEP devices, in which 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.

Primary ciliary dyskinesia (PCD) - usually an autosomal recessive genetic condition in which the microscopic organelles (cilia) in the respiratory system have defective function. Ciliary dysfunction prevents the clearance of mucous from the lungs, paranasal sinuses and middle ears.

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 this policy.

1. Initial use of a high-frequency chest wall oscillation (HFCWO) device (HCPCS code E0483) is considered medically necessary when ALL of the following criteria are met:
    A. The device is cleared by the FDA; AND
    B. The device use is ongoing (that is, compliance with use) and is documented at four (4) to six (6) week trial intervals; AND
    C. There is documented need for airway clearance; AND
    D. The device is prescribed by either a pulmonologist or a specialty clinic; AND
    E. The patient has ANY ONE of the following diagnoses documented in the medical record:
        1) Cystic fibrosis (CF); OR
        2) Immotile Cilia Syndrome (aka Primary Ciliary Dyskinesia); OR
        3) Chronic bronchiectasis-as defined by daily productive cough for at least six (6) continuous months, or more than two (2) exacerbations per year, requiring antibiotic therapy and confirmed by high resolution, spiral, or standard chest CT scan; OR
        4) Chronic neuromuscular disorder affecting the ability to cough or clear respiratory secretions, with prior history of pneumonia or other significant worsening of pulmonary function, and the patient also has ANY ONE of the following neuromuscular disease diagnoses:
            a) Acid maltase deficiency; OR
            b) Anterior horn cell diseases, including amyotrophic lateral sclerosis; OR
            c) Quadriplegia regardless of underlying etiology; OR
            d) Multiple sclerosis; OR
            e) Post-polio; OR
            f) Hereditary muscular dystrophy; OR
            g) Myotonic disorders; OR
            h) Paralysis of the diaphragm; OR
            i) Other myopathies; AND
    F. There is a demonstrated presence of bronchopulmonary secretions with need for airway clearance; AND
    G. Conventional manual chest PT (CPT) is unavailable, ineffective, or not tolerated as age appropriate, with documented failure of standard treatments (CPT 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. Valid reasons may include, but are not limited to ANY of the following situations:
        1) physical or emotional disability; OR
        2) time limitations; OR

3) the severity of the pulmonary disease requires complex or frequent therapy; OR
4) the patient is an independent individual without a capable caregiver.

Note: For HFCWO devices with usage meters, documentation should reflect use, in general, of at least 67% of the prescribed time.

2. Devices
The Flutter® valve and Acapella® devices (HCPCS codes E0484, S8185) 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.

3. Contraindications
Contraindications exist for external manipulation of the thorax, 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
    - complaint of significant chest wall pain

4. When HFCWO oscillation devices are not medically necessary
    - These devices will be considered not medically necessary for conditions other than those listed above because the scientific evidence has not been established.

    - Intrapulmonary percussive ventilatory (IPV) devices (HCPCS code E0481) 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 HFCWO for all other conditions is considered not medically necessary.

    - The 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.

- HFCWO oscillation device replacement or upgrade is considered not medically necessary when requested for convenience or to upgrade to a newer technology when the current components remain functional.

- The use of both an HFCWO device and a mechanical in-exsufflation device is considered not medically necessary.

5. Durable Medical Equipment (DME)
   The HFCWO device (HCPCS code E0483) is classified as a DME rental item and may be subject to prior authorization requirements. Continued use of a HFCWO device is considered medically necessary when ongoing use, (compliance with use) is documented at monthly intervals.

   Note: For HFCWO devices with usage meters, documentation should reflect use, in general, at least 67% of the prescribed time.

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

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

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.
- AerobiKA Oscillating PEP device in 2013.
- Monarch Airway Clearance System in 2017
- MedPulse Respiratory Vest System (Electromed, Inc., Minnetonka, MN) in 1999

In 2007, 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

CMS
The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- Local Coverage Determination (LCD) High Frequency Chest Wall Oscillation Devices (L33785)
- Local Coverage Article (LCA) High Frequency Chest Wall Oscillation Devices (A52494)

Summary of Literature

High-frequency chest-wall compression (HFCC) and high-frequency chest-wall oscillation (HFCWO) and are two methods used for airway clearance. Airway clearance techniques fall into two broad categories, unassisted and assisted. The word "assist" in this context means that the respiratory device (eg, ventilator) does work on the respiratory system. Unassisted methods rely on the energy from passive exhalation to generate chest-wall oscillations. In contrast, active devices such as the intrapulmonary percussive ventilator, the various "vest" devices, and external high-frequency external oscillators create either a positive or negative transrespiratory pressure change to generate high- frequency, small-volume oscillations in the airways (RT Magazine, 2008).

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 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.

The American College of Chest Physicians' (CHEST) evidence-based clinical practice guidelines on non-pharmacologic airway clearance therapies recommend oscillatory devices (e.g., Flutter, IPV, and HFCWO) be considered as an alternative to chest physiotherapy only in CF patients (McCool and Rosen, 2006).

Rationale
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 patients or 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, 23 completed (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.

Nicolini (2018) conducted a study to test the effectiveness of high-frequency chest wall compression (HFCWC) in patients with bronchiectasis. 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. Both treatments (traditional CPT and HFCWO) showed a significant 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 a significant improvement in blood inflammation parameter C-RP ($p \leq 0.019$), parameters of lung functionality associated with bronchial obstruction (FVC, FEV1) ($p \leq 0.006$ and $p \leq 0.001$), and in the dyspnea. Improvement in quality of life scales was noted. (BCSS, CAT) (both $p \leq 0.001$). No significant changes of total cell counts in sputum samples were observed in the two groups. In the HFCWO group a significant reduction of neutrophils percentage ($p \leq 0.002$) and a significant

increase of macrophages percentage (p ≤0.012). The HFCWO technique provides an improvement both in pulmonary function and quality of life related parameters in patients with chronic hypersecretive disease. Since those patients need daily airway clearance, this treatment should be included among the principal options in chest physiotherapy.

Coding Requirements

Procedure Codes

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
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E0483	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
S8185	Flutter device

Non-covered Procedure Code

Requests for the service below must be referred to a Medical Director for approval.

HCPCS Code	Description
E0481	Intrapulmonary percussive ventilation system and related accessories

Diagnosis Codes

ICD-10 Code	Description
A15.0	Tuberculous of lung
B91	Sequelae of poliomyelitis
E74.00	Glycogen storage disease, unspecified
E74.01	von Gierke disease
E74.04	McArdle disease
E74.09	Other glycogen storage disease
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E84.0	Cystic fibrosis with pulmonary manifestations
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis unspecified
G12.0	Infantile spinal muscular atrophy, type 1 (Werdnig-Hoffman)
G12.1	Other inherited spinal muscular atrophy
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy

G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle dystrophy
G12.29	Other motor neuron disease
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Postpolio syndrome
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
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G71.12	Motonia congenita
G71.13	Myotonic chondrodystrophy
G71.14	Drug induced myotonia
G71.19	Other specified myotonic disorders
G71.20	Congenital myopathy, unspecified
G71.21	Nemaline myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
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
G82.54	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
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	Sjogren syndrome with myopathy

R53.2	Functional quadriplegia
Q33.4	Congenital bronchiectasis

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) High Frequency Chest Wall Oscillation Devices (L33785). Original Effective date October 1, 2015. Revision Date October 1, 2022. Accessed on September 29, 2023.

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