

Airway Clearance Devices

Policy Number: PG0227

Last Reviewed Date: 04/01/2025

Last Revised: 4/1/2025

HMO AND PPO

ELITE (MEDICARE ADVANTAGE)

MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

☒ Professional

☐ Facility

DESCRIPTION:

Individuals with impaired ability to cough due to respiratory muscle weakness or pulmonary restriction have difficulty clearing secretions from the lungs. The accumulated secretions may allow growth of pathogens, leading to a higher risk for chronic infections, inflammation, and deterioration of lung function as the bronchial tubes can be occluded. Conditions that can lead to this problem include amyotrophic lateral sclerosis (ALS), chronic bronchitis, bronchiectasis, immotile cilia syndrome, cystic fibrosis (CF), muscular dystrophy, myasthenia gravis and spinal cord injuries.

Airway oscillating clearance devices have been utilized as an alternative to conventional chest physiotherapy, which includes percussion, postural drainage, forced expiratory maneuvers, huffing and coughing. These techniques usually require the aid of another person. Several types of airway clearance devices have been developed and have been most often associated and studied in the treatment of CF. High frequency chest wall oscillation represents a mechanical form of chest physiotherapy utilized to enhance mobilization of pulmonary secretions. Airway oscillating devices (e.g., Flutter and Acapella) are considered medically necessary for cystic fibrosis (CF), chronic bronchitis, bronchiectasis, immotile cilia syndrome (also known as primary ciliary dyskinesia) and asthma.

Mechanical percussors are electrical devices used to provide clapping or percussion to the external chest wall. The devices deliver consistent, programmable (i.e., adjustable speed) deep pulses. The machine is moved over the patient's chest while the patient assumes a variety of drainage positions. The hand clapping performed during conventional CPT is mimicked by the machine and is less fatiguing than manual hand percussion. Mechanical percussors (e.g., Fluid Flo, Freuencer, and VibraLung Acoustical Percussor) are considered medically necessary for CF, chronic bronchitis, bronchiectasis, immotile cilia syndrome, and asthma.

Positive expiratory resistance or positive expiratory pressure (PEP) devices promote mucus clearance by preventing airway closure and increasing collateral ventilation. PEP pushes air into the lungs behind mucus, holds the airways open, and keeps them from closing. An oscillating positive expiratory pressure device (PEP)

creates vibrations as a person breathes into a handheld device. The person breathes in normally but breathes out harder against resistance. The device consists of a one-way valve connected to a small-exit orifice or an adjustable expiratory resistor. PEP therapy can be taught to children as young as age five years and can be passively given to infants via masks. Positive expiratory pressure (PEP) mask is considered medically necessary for CF, chronic bronchitis, immotile cilia syndrome, asthma, and chronic obstructive pulmonary disease (COPD).

Another airway clearance device is the **oscillatory (or vibratory) positive expiratory pressure**, a form of PEP that employs deep breathing and forced exhalation to achieve airway clearance via small, hand-held devices. This device is beneficial to patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations. These devices combine high-frequency airflow oscillations with PEP using a stainless-steel ball or a counterweight plug and magnet to create airflow oscillations. For children as young as two years of age, vibratory PEP can be administered via a mask. For older patients (i.e., over age five) the treatment may be administered via a mouthpiece.

When conventional postural drainage therapy and other devices have failed or are contraindicated, **high-frequency chest wall oscillation vests** may be a treatment option for patients with cystic fibrosis or bronchiectasis. These devices consist of an air generator and an inflatable vest that covers the chest. Increases in air pulses are delivered to the vest with altering airflow patterns, causing external manipulations of the chest. This external chest wall vibration produced by high frequency chest wall oscillation is thought to reduce mucus viscosity and improve clearance of respiratory tract secretions. Examples of these devices include, but may not be limited to, the Vest Airway Clearance System (formally known as ThAIRapy Vest or ABI Vest), the SmartVest Airway Clearance System, the SQL SmartVest Airway Clearance System, the InCourage System, AffloVest, the "Frequencer, the Monarch Airway Clearance System and the Medpulse Respiratory Vest System.

Patients with neuromuscular disorders can have significantly impaired chest wall and/or diaphragm action decreasing the ability to mobilize and remove secretions from the airways. **Mechanical insufflator-exsufflators (MI-Es)**, (e.g., VitalCough™) also known as cough assist therapy, are portable electric devices that alternately apply positive and rapid negative pressure to a patient's airway and are considered an established treatment option for patients with neuromuscular disorders with compromised chest wall or diaphragmatic movement. MI-Es create a rapid shift in pressure producing a high expiratory flow rate from the lungs, stimulating cough, and increasing secretion clearance. Mechanical insufflator-exsufflators devices are considered medically necessary for persons with a neuromuscular disease (e.g., amyotrophic lateral sclerosis, congenital myopathies, inclusion body myositis, muscular dystrophy, myasthenia gravis, poliomyelitis, progressive bulbar palsy, spinal muscular atrophy, high spinal cord injury with quadriplegia) that is causing a significant impairment of chest wall and/or diaphragmatic movement and for whom standard treatments (e.g., chest percussion and postural drainage, etc.) have not been successful in adequately mobilizing retained secretions.

Vibralung® (Westmed Inc., Tucson, AZ) is an example of a **combination device** that can be used as an acoustical percussor and a positive expiratory pressure device and, when needed, an aerosol drug delivery system. Vibralung is also referred to as an electro-mechanical acoustical airway clearance (EMAAC) device. The device includes a handheld transducer (HHT) with a variable expiratory resistor attached to a mouthpiece. The HHT is connected to the electronic frequency generator, called the treatment control unit (TCU). When turned on, the device creates sound waves to cause vibrations/percussions in the airways to loosen and mobilize secretions. The patient can select the intensity of the treatment by adjusting the dials on the TCU. The variable expiratory resistor (VER) provides PEP with oscillation. The patient can adjust the orifice to provide minimum to maximum PEP. Vibralung can be interfaced with Westmed's Circulair II Hybrid aerosol drug delivery system to deliver medications during the treatment. Because Vibralung does not make contact with the chest wall, it is proposed that it may be gentler than oscillatory PEP devices and devices that do make chest wall contact. Therefore, Vibralung is proposed for use in conditions where other standard airway clearance devices (e.g., mechanical percussors, positive expiratory pressure device, oscillatory device, high-frequency chest wall compression device) fail to produce the necessary clinical outcome, are contraindicated, or cannot be used because of chest injuries such as fractured ribs, burns or acute surgical wounds.

Intrapulmonary percussive ventilation (IPPV) or High- Frequency Chest Compression Systems is a form of chest physiotherapy producing internal high frequency airway vibration in contrast to external chest wall vibration. IPV is a modified method of intermittent positive-pressure breathing, with superimposed high-frequency mini-bursts of air or oxygen into the lungs while simultaneously delivering therapeutic aerosols. The combination of vibrations, aerosol, and pressure loosens secretions, stimulates cough, and leads to sputum production. Although typically utilized during hospitalization, IPPV has been proposed for in-home use.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Effective 2/1/2020: Airway clearance devices require a prior authorization for all product lines; may not be an all-inclusive listing (Limits may apply):**
 - **High Frequency Oscillation Systems (A7025, A7026, E0483)**
 - **Mechanical insufflation-exsufflation devices (A7020, E0482)**
 - **Positive expiratory pressure devices (E1399)**
 - **Mechanical percussors (E0480)**
 - **Oscillatory (vibratory) positive expiratory pressure devices (E0484)**
 - **Acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination devices (e.g., Vibr Lung®) (E1399)**
- **Intrapulmonary percussive ventilation devices (E0481) are non-covered**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Airway Clearance Devices (E0480, E0484, E1399)

ANY of the following of airway clearance devices is considered medically necessary durable medical equipment (DME) for a member with a diagnosis (e.g., cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome-also known as primary ciliary dyskinesia, COPD, asthma) that is characterized by hypersecretory lung disease (i.e., excessive mucus production) and difficulty clearing secretions:

- Mechanical percussors (E0480) (e.g., Fluid Flo, Frequenter, and VibriLung Acoustical Percussor)
- Positive expiratory pressure (PEP) devices (E1399)
- Oscillatory (vibratory) positive expiratory pressure devices (E0484) (e.g., Flutter and Acapella)

High Frequency Chest Wall Oscillation Systems (E0483, A7025, A7026)

Paramount covers High Frequency Chest Wall Oscillation Systems (E0483, A7025, A7026) when it is medically necessary, and all the following criteria is met:

1. An FDA approved device is prescribed; **AND**
2. Documented need for airway clearance and at least one of the following clinical conditions;
 - a. Diagnosis of Cystic Fibrosis; **OR**
 - b. Diagnosis of Immotile Cilia Syndrome; **OR**
 - c. Diagnosis of bronchiectasis, confirmed by CT scan, characterized by daily productive cough for 6 continuous months or by frequent (i.e., > two times/year) exacerbations requiring antibiotic therapy; **OR**
 - d. Chronic Neuromuscular Disorder (i.e., quadriplegia, multiple sclerosis, hereditary muscular dystrophy, post-polio, paralysis of the diaphragm, amyotrophic lateral sclerosis, myotonic disorders, etc.); **AND**
3. Documentation of medical necessity for chest physiotherapy at least twice a day, **AND**
4. Patient unable to do standard chest physiotherapy due to:
 - a. Primary caregiver unable to provide therapy consistently and effectively due to:
 - Physical disability or limitations of the caregiver including musculoskeletal syndromes, arthritis or other disabling condition, **OR**
 - Other factors or circumstances which prevent caregiver from providing chest physiotherapy according to the medical care plan, including single working parent and household with more than one (1) child with CF, **OR**
 - b. The patient is an independent college student or an adult and a caregiver or other resource is not available to administer the chest physiotherapy according to the medical care plan, **OR**

- c. Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy, **OR**
- d. Standard chest physiotherapy has been administered in accordance with the medical care plan, but has proven to be ineffective in achieving the desired outcome, **AND**
- 5. There must be no contraindications for the use of the Chest wall oscillation vest – Airway clearance system.

High Frequency Chest Wall Oscillation Systems are CONTRAINDICATED and non-covered if the member has, not all-inclusive listing:

- Unstable head injury
- Unstable neck injury
- Active Hemorrhage with hemodynamic instability
- Subcutaneous emphysema
- Recent (within the past 90 days) epidural spinal infusion/anesthesia
- Recent (within the past 90 days) skin grafts or flaps on the thorax
- Osteoporosis
- Burns, open wounds and/or skin infections of the thorax
- Recently placed (within the past 90 days) transvenous pacemaker or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Complaint of chest wall pain
- Bronchopleural fistula
- Coagulopathy
- Intracranial pressure (ICP) >20 mm Hg
- Pulmonary edema associated with congestive heart failure (CHF)

Continued coverage for High Frequency Chest Wall Oscillation Systems will be provided when that members compliance, effective utilization and significant benefit from the high frequency chest wall oscillation system have been demonstrated during the three-month trial period. Medical record documentation must include frequency and duration of treatments and system meter usage prior to consideration of system purchase.

Coverage for High Frequency Chest Wall Oscillation Systems will be DISCONTINUED upon:

- Member and/or prescribing physician request, **OR**
- Member treatment compliance at a rate of less than 50% usage as prescribed in the medical treatment plan, to be checked at two (2) and six (6) months of usage, **OR**
- There has been no significant benefit established.

Mechanical insufflation-exsufflation devices (A7020, E0482)

Mechanical insufflation-exsufflation devices (A7020, E0482) are considered medically necessary for a member with a neuromuscular disorder (e.g., muscular dystrophy, multiple sclerosis, amyotrophic lateral sclerosis, congenital myopathies, inclusion body myositis, myasthenia gravis, poliomyelitis, progressive bulbar palsy, spinal muscular atrophy, high spinal cord injury with quadriplegia) that is causing significant impairment of chest wall and/or diaphragmatic movement resulting in difficulty clearing secretions.

Combination devices (e.g., Vibralung®) (E1399)

Acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination devices (e.g., Vibralung®) (E1399) are considered medically necessary when BOTH of the following criteria are met:

- Diagnosis (e.g., cystic fibrosis, chronic bronchitis) that is characterized by excessive mucus production, infection and difficulty clearing secretions
- Failure, intolerance, or contraindication to a standard airway clearance device (e.g., mechanical percussors, positive expiratory pressure device, oscillatory device, high-frequency chest wall compression device) due to chest wall injury (e.g., fractured ribs, burns)

Exclusions:

- Intrapulmonary percussive ventilation (E0481) is noncovered, as it has not demonstrated equivalence or superiority to currently accepted standard means of treatment. Intrapulmonary percussive ventilators (IPV) (e.g., the Impulsator F00012) for all indications (e.g., bronchiectasis, COPD, CF, neuromuscular conditions associated with retained airway secretions or atelectasis, and post-operative pulmonary complications; not an all-inclusive list) because there is insufficient evidence supporting their effectiveness; Intrapulmonary percussive ventilation devices (E0481) are considered experimental/investigational.
- High-frequency oscillation therapy for the treatment of bronchitis, and secretion-induced atelectasis because there is insufficient evidence supporting its effectiveness;
- Continuous high-frequency oscillations therapy is noncovered as it is considered experimental/investigational. Continuous high-frequency oscillation therapy for the treatment of secretion-induced atelectasis is considered experimental/investigational because there is insufficient evidence supporting its effectiveness.
- The Volara System Oscillation & Lung Expansion (OLE) therapy device for the treatment of asthma, cystic fibrosis, middle lobe syndrome, and other respiratory disorders because there is insufficient evidence supporting its effectiveness.
- The Simeox Airway Clearance Technology bronchial drainage device for the treatment of cystic fibrosis and all other indications because there is insufficient evidence supporting their effectiveness.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODES	
A7020	Interface for cough stimulating device, includes all components, replacement only
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter) (New 10/1/2024)
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (New 10/1/2024)
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussive ventilation system and related accessories
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E1399	Durable medical equipment, miscellaneous

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 08/15/2009

Date	Explanation & Changes
01/22/2002	<ul style="list-style-type: none"> • Changes
08/28/2003	<ul style="list-style-type: none"> • HCPCS updated
04/18/2014	<ul style="list-style-type: none"> • Chest Wall Oscillation Vest continues to be covered with prior authorization for all product line • Policy reviewed and updated to reflect most current clinical evidence per TAWG committee

04/23/2015	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per TAWG committee
05/27/2016	<ul style="list-style-type: none"> Chest Wall Oscillation Vests (E0483) no longer require prior authorization for all product lines Policy reviewed and updated to reflect most current clinical evidence per TAWG committee
10/27/2017	<ul style="list-style-type: none"> Changed title from PG0227 Chest Wall Oscillation Vest to Airway Clearance Devices Added codes E0480, E0482, E0484 as covered without prior authorization for all product lines Added unlisted code E1399 Added code E0481 as covered without prior authorization for Advantage and non-covered for HMO, PPO, Individual Marketplace, & Elite Added code S8185 as non-covered for all product lines Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
08/22/2019	<ul style="list-style-type: none"> Updated Policy. Add procedure A7020. Added covered ICD-10 Diagnosis
12/31/2019	<ul style="list-style-type: none"> Updated Policy to indicate Prior Authorization requirements for Airway Clearance Devices
12/16/2020	<ul style="list-style-type: none"> Medical policy placed on the new Paramount Medical Policy Format
02/15/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/30/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/05/2024	<ul style="list-style-type: none"> Medical Policy placed on the new Paramount Medical Policy format
05/01/2024	<ul style="list-style-type: none"> Medical Policy reviewed and updated to reflect the most current clinical evidence Removed non-covered code S8185 Removed ICD-10 diagnosis codes
04/01/2025	<ul style="list-style-type: none"> Medical policy reviewed and updated to reflect the most current clinical evidence Added, non-covered codes, A7021 and E0469, new codes effective 10/1/2024

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies

<https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting

<https://www.cms.gov/medicare/coding/icd10>

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services <https://www.cms.gov/medicare-medicare-coordination/national-correct-coding-initiative-ncci/ncci-medicare>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) <https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits>
U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review