GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

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 and deterioration of lung function as the bronchial tubes can be occluded. Conditions that can lead to this problem include amyotrophic lateral sclerosis (ALS), bronchiectasis, cystic fibrosis (CF), muscular dystrophy, myasthenia gravis and spinal cord injuries.

Airway 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.

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. 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 and the Medpulse Respiratory Vest System.

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.

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. 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.

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. These devices combine high-frequency air flow 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.

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), 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.

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 orifice can be adjusted by the patient 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 (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**

<table>
<thead>
<tr>
<th>These airway clearance devices do not require prior authorization for all product lines (Limits may apply):</th>
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<tbody>
<tr>
<td>• Mechanical percussors (E0480)</td>
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<tr>
<td>• Positive expiratory pressure devices (E1399)</td>
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<tr>
<td>• Oscillatory (vibratory) positive expiratory pressure devices (E0484)</td>
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<tr>
<td>• Chest Wall Oscillation Vests (E0483)</td>
</tr>
<tr>
<td>• Mechanical insufflation-exsufflation devices (E0482)</td>
</tr>
<tr>
<td>• Acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination devices (e.g., Vibralung®) (E1399)</td>
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Intrapulmonary percussive ventilation devices (E0481) do not require prior authorization for Advantage.

Intrapulmonary percussive ventilation devices (E0481) are non-covered for HMO, PPO, Individual Marketplace, & Elite.

Code S8185 is non-covered for all product lines.

Airway Clearance Devices (E0480, E0484, E1399)

ANY of the following types of airway clearance devices is considered medically necessary for an individual with a diagnosis (e.g., cystic fibrosis, chronic bronchitis) that is characterized by excessive mucus production and difficulty clearing secretions:

• Mechanical percussors (E0480)
• Positive expiratory pressure devices (E1399)
• Oscillatory (vibratory) positive expiratory pressure devices (E0484)

Chest Wall Oscillation Vests (E0483)

Paramount covers Chest Wall Oscillation Vests (E0483) when it is medically necessary and all of the following criteria is met:

1. Diagnosis of Cystic Fibrosis or other serious medical condition with significant problems in bronchial mucous secretion clearance, AND
2. Documentation of medical necessity for chest physiotherapy at least twice a day, AND
3. 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. 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
d. There must be no contraindications for the use of the Chest wall oscillation vest – Airway clearance system.

Chest Wall Oscillation Vests are CONTRAINDICATED and non-covered if the member has:

- Unstable head injury
- Unstable neck injury
- Active Hemorrhage with hemodynamic instability
- Subcutaneous emphysema
- Recent epidural spinal infusion/anesthesia
- Recent skin grafts or flaps on the thorax
- Osteoporosis
- Burns, open wounds and/or skin infections of the thorax
- Recently placed transvenous pacemaker or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Complaint of chest wall pain

Coverage for Chest Wall Oscillation Vests 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.

Mechanical insufflation-exsufflation devices (E0482)

Mechanical insufflation-exsufflation devices (E0482) are considered medically necessary for an individual with a neuromuscular disorder (e.g., muscular dystrophy, multiple sclerosis) with 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)

Advantage

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of intrapulmonary percussive ventilation devices (E0481), The Ohio Department of Medicaid requires this procedure be covered for Advantage members.

HMO, PPO, Individual Marketplace, Elite

Intrapulmonary percussive ventilation devices (E0481) are considered experimental, investigational or unproven.

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.

<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each</td>
</tr>
<tr>
<td>A7026</td>
<td>High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each</td>
</tr>
<tr>
<td>E0480</td>
<td>Percussor, electric or pneumatic, home model</td>
</tr>
<tr>
<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and related accessories</td>
</tr>
<tr>
<td>E0482</td>
<td>Cough stimulating device, alternating positive and negative airway pressure</td>
</tr>
<tr>
<td>E0483</td>
<td>High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
</tr>
<tr>
<td>E0484</td>
<td>Oscillatory positive expiratory pressure device, non-electric, any type, each</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td>S8185</td>
<td>Flutter device</td>
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</tbody>
</table>

REVISION HISTORY EXPLANATION
01/22/02: Changes
08/28/03: HCPCS updated
04/18/14: Chest Wall Oscillation Vest continues to be covered with prior authorization for all product lines Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.
04/23/15: Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.
05/27/16: Policy reviewed and updated to reflect most current clinical evidence per TAWG committee.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.