Airway Clearance Devices in the Ambulatory Setting

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Coverage for airway clearance devices is subject to the terms, conditions and limitations of the applicable benefit plan’s Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for airway clearance devices is available, the following conditions of coverage apply.

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 (HCPCS E0480)
- positive expiratory pressure devices (HCPCS E1399)
- oscillatory (vibratory) positive expiratory pressure devices (HCPCS E0484; S8185)
A mechanical insufflation-exsufflation device (HCPCS E0482) is 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.

A high-frequency chest wall compression device (HCPCS E0483) is considered medically necessary for EITHER of the following conditions:

- cystic fibrosis, when there is failure, contraindication or intolerance to home chest physiotherapy or it cannot be provided
- bronchiectasis confirmed by high-resolution computed tomography (CT) and characterized by BOTH of the following:
  - daily productive cough for at least six continuous months OR frequent exacerbations requiring antibiotic therapy more than two times per year
  - failure of standard treatments (e.g. pharmacotherapy, postural drainage, chest percussion, vibration) to mobilize secretions

An acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination device (e.g., Vibralung®; E1399) is 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)

An intrapulmonary percussive ventilation device (E0481) for home use is considered experimental, investigational or unproven.

Overview

This Coverage Policy addresses various airway clearance devices that are utilized for the treatment of respiratory disorders characterized by excessive respiratory secretions and impaired airway clearance. These devices include: mechanical percussor, positive expiratory pressure, oscillatory (vibratory) positive expiratory pressure, mechanical insufflation-exsufflation, high-frequency chest wall compression, and combination device (i.e., acoustical percussor, positive expiratory pressure and aerosol drug delivery system).

General Background

Respiratory disorders characterized by excessive respiratory secretions and impaired airway clearance include cystic fibrosis, chronic bronchitis, emphysema with a chronic bronchitic component, chronic asthma, dyskinetic cilia syndromes, diffuse panbronchiolitis, and idiopathic bronchiectasis. Neuromuscular diseases, such as muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS) can also result in the inability of the patient to effectively clear mucus from the airways.

Cystic fibrosis (CF) is a major cause of severe chronic lung disease in children and is characterized by obstruction and infection of airways. CF produces thick, sticky mucus that clogs airways and breathing passages. An important activity of daily living for the CF patient is clearing of the lungs. This may be accomplished by chest percussion, mucus thinning drugs and antibiotics.

Bronchiectasis refers to anatomical distortion of the conducting airways (i.e., thickening, herniation, or dilation) and is characterized clinically by chronic respiratory symptoms, such as cough and sputum production. The use of antibiotics and efforts at improved pulmonary clearance allow some control of disease progression. Treatment may also include bronchodilators, expectorants, hydration, chest percussion, postural drainage therapy (PDT),...
also referred to as chest physical therapy (CPT) and other maneuvers designed to mobilize secretions. Treatment rarely eradicates the infection completely and does not significantly reverse the anatomical changes (Morrissey, 2004).

When patients are experiencing excessive mucus and having difficulty clearing secretions using standard therapy, mechanical devices may be indicated. The various types of devices include mechanical percussors, positive expiratory pressure (PEP), oscillatory (vibratory) positive expiratory pressure devices, mechanical insufflation-exsufflation, and high-frequency chest wall compression (HFCWC) (Hristara-Papadopoulou, et al., 2008; Yankaskas, 2004; Wagener, 2003). Although intrapulmonary percussive ventilation devices have been proposed for in-home use their safety and efficacy for this indication have not been established.

**Mechanical Percussors**

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.

Percussors are approved as Class II 510(k) medical devices by the U.S. Food and Drug Administration (FDA). The Fluid Flo Model 2500 Percussor, Electro Flo® 5000 (MED Systems, San Diego, CA) and the Frequencer V2™ and Frequencer V2x™ (Dymedso Inc., Canada), are examples of mechanical percussors. Per the FDA, indications for use for the Frequencer is to provide “airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of chest physiotherapy by providing a convenient method of external thorax manipulation. It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma, muscular dystrophy, neuromuscular degenerative disorders, postoperative atelectasis and thoracic wall defects” (FDA, 2011).

Although there are a limited number of published studies comparing mechanical percussion to standard airway clearance therapies (Cantin, et al., 2006), mechanical percussion is considered an established option for clearance of mucus for conditions in which excessive mucus production is present and the patient has difficulty clearing secretions.

**Positive Expiratory Pressure**

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.

PEP devices are considered Class II medical devices and are regulated by the FDA. Examples of this type of device are the TheraPEP® (DHD Healthcare, Wampsville, NY) and the Pari Pep™ device (PARI Respiratory Equipment, Inc., Midlothian, VA). TheraPEP is indicated for the treatment of patients with cystic fibrosis, lung disease with secretory problems and to prevent or reverse atelectasis. The Pari Pep device is designed to help patients exercise their lungs and improve secretion clearance. It can be used by adults or children in the home.

Systematic reviews, randomized controlled trials, and case series reported that cough scores and physical activity improved following PEP, and that PEP was as effective as other forms of physiotherapy when patients are having difficulty clearing excessive mucus secretions (McIlwaine, et al., 2015; McIlwaine, et al., 2013; Nicolini, et al., Mar 2013; Su, et al., 2007; Elkins, et al., 2006; Darbee, et al., 2004).

**Oscillatory Positive Expiratory Pressure**

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.

Examples of these Class II 510(k) devices are the Flutter® (Scandipharm, Birmingham, AL), the Acapella® (DHD Healthcare, Wampsville, NY) and the RC Cornet® device (Pari Respiratory Equipment, Midlothian, VA). The Flutter device is used to assist in the clearance of excessive secretions from the lungs of patients with cystic fibrosis, bronchitis, bronchiectasis and other diseases associated with excessive amounts of mucous. The Acapella and RC Cornet operate on the same principle as the flutter, but are not gravity dependent.

Randomized controlled trials have compared vibratory or oscillating PEP therapy (e.g., Flutter, Acapella) to chest physiotherapy, PEP, and active cycles of breathing techniques for airway clearance in patients with diseases such as cystic fibrosis and bronchiectasis. Reported outcomes included improvement in pulmonary function values, amount and weight of sputum, cough frequency, and duration of therapy (Lee, et al., 2015; Pryor, et al., 2010; Eaton, et al., 2007; Patterson, et al., 2007; McCarren and Alison, 2006; Lagerkvist, et al., 2006; Patterson, et al., 2005; Thompson, et al., 2002; Oermann, et al., 2001).

Mechanical Insufflation-Exsufflation
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.

MI-Es are regulated by the FDA as Class II medical devices. An example of this device is the CoughAssist™ (J.H. Emerson Co., Cambridge, MA). The CoughAssist delivers air via a breathing circuit incorporating a flexible tube, a bacterial filter, and either a facemask, mouthpiece or endotracheal or tracheostomy tube. The intended use is to “assist patients in clearing retained bronchopulmonary secretions by gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure” (FDA, 2000). Mechanical insufflation-exsufflation therapy can be provided in the home with assistance from a family member or health professional.

Systematic reviews, randomized controlled trials and case series support the use of an MI-E device for airway management in patients with neuromuscular disorders. Decreased breathlessness and improved oxygenation, pulmonary function values, and sputum production were reported (Arcuri, et al., 2016; Hayes, 2017; Fauroux, et al., 2008; Sancho, et al., 2004; Miske, et al., 2004; Winck, et al., 2004; Chatwin, et al., 2003).

High-Frequency Chest Wall Compression
When conventional postural drainage therapy and other devices have failed or are contraindicated, high-frequency chest wall compression (HFCWC) may be a treatment option for patients with cystic fibrosis or bronchiectasis. HFCWC, a mechanical form of chest physiotherapy, is a system composed of a fitted vest coupled to a pneumatic compressor that uses high frequency oscillation to provide chest physiotherapy. The compressor inflates and deflates the vest, compressing and releasing the chest wall to create airflow within the lungs. The vibrations, along with the increase in airflow, help loosen mucus from the lungs. Children as young as three years of age are able to use the vest (Wagener, et al., 2003). HFCWC is an established airway clearance device for patients with cystic fibrosis who cannot tolerate chest physiotherapy or in whom chest physiotherapy is ineffective or is contraindicated. HFCWC may also be indicated for patients with chronic bronchiectasis (i.e., continuous for six months) confirmed by high-resolution computed tomography (CT) or patients with frequent exacerbations requiring antibiotic therapy who have fail conventional forms of clearing secretions.

Approved by the FDA 510(k) class II process, these devices include the Vest™ Airway Clearance System (Hill-Rom, St. Paul, MN; previously manufactured by Advanced Respiratory, St. Paul, MN), the SmartVest Airway Clearance System (Electomed, Inc., New Prague, MN); inCourage System (RespirTech, Inc., St. Paul, MN) and RespIn 11 Bronchial Airway Clearance System (Respinnovations SAS, Seillans, France). The devices are approved by the FDA to promote airway clearance or improve bronchial drainage by enhancing mobilization of
bronchial secretions when external manipulation of the thorax is the choice of treatment in patients who are retaining secretions and having difficulty with clearance (FDA 2012; FDA, 2000).

Systematic reviews randomized controlled trials and case series demonstrated that HFCWC is an effective therapy for airway clearance for a defined subpopulation with cystic fibrosis or bronchiectasis. Randomized controlled trials compared the use of HFCWC to chest physical therapy, oscillatory PEP, or no therapy. Improvements were seen in pulmonary function values, sputum production, antibiotic use, and/or frequency of hospitalization. HFCWC was noted to be well tolerated, improved breathing, and decreased fatigue in this subpopulation (Lee, et al., 2015; Nicolini, et al., Apr 2013; Chakravorty, et al., 2011; Fainardi, et al., 2011; Yuan, et al., 2010; Lange, et al., 2006; Oermann, et al., 2001).

Some studies have investigated HFCW for conditions not related to cystic fibrosis (CF) (e.g., asthma, COPD, neuromuscular disorders) suggesting that vest therapy may be a treatment option for clearing the airway. In a 2014 directory report (reviewed 2017), Hayes reported the results of a systematic review of the literature to investigate HFCW for non-CF conditions (e.g., COPD, ALS, asthma, postoperative, bronchiectasis). Systematic reviews, randomized controlled trials and prospective case studies met inclusion criteria. The studies included small patient populations, various comparators (e.g., chest physiotherapy, usual care, sham), short-term follow-ups and conflicting outcomes. Hayes concluded that based on low quality evidence HFCWC may be beneficial to disorders of airway clearance other than cystic fibrosis for adults, but patient selection criteria have not been established. Data on safety and effectiveness in children is lacking. Annual reviews of the literature have revealed no new data to support use of HFCW in these other conditions.

Acoustical Percussor, Positive Expiratory Pressure and Aerosol Drug Delivery System Combination Device

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 (Westmed, 2016).

Vibralung is FDA 510(k) approved as an electric powered percussor and a predicate device to the Frequencer, Acapella and Lung Flute (Medical Acoustics, LLC, Buffalo, NY). The device is indicated as an airway secretion clearance device that creates vibrations and as a lung expansion device that applies positive expiratory pressure (PEP) as the patient breathes through the device. It may be used simultaneously with its aerosol drug delivery system. Patients with cystic fibrosis, COPD, asthma, lung diseases with secretory problems, and neuromuscular disease affecting the ability to effectively cough may be a candidate for the device (FDA, 2014).

Published studies comparing Vibralung to other types of airway clearance devices are lacking. Vibralung has not been proven to be superior to conventional airway clearance devices. Therefore Vibralung is indicated when standard devices (e.g., mechanical percussors, positive expiratory pressure device, oscillatory device, high-frequency chest wall compression device) cannot be utilized due to chest wall injury (e.g., fractured ribs, burns).

Intrapulmonary Percussive Ventilation

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.

IPVs are approved by the FDA 510(k) process. There are multiple IPVs manufactured by Percussionaire Corporation (Sandpoint, ID), including institutional and home devices. An example of a home care device is the HC Impulsator®.

There is a paucity of evidence supporting the safety and efficacy of IPVs for home use. Studies are primarily in the form of case reports or case series with small patient populations and short-term follow-up (Marks, et al., 2004). Some studies reported no statistically significant differences in outcomes with IPV devices. In a 2016 search and summary, Hayes concluded that there was insufficient evidence to support IPV home use for children. Studies included one prospective case series (n=6) and case reports.

Professional Societies/Organizations
American Academy of Neurology (AAN): In their practice parameters on the care of patients with amyotrophic lateral sclerosis (2009; reaffirmed 2014), AAN recommendations included MI-E to aid in clearing secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection.

American College of Chest Physicians (ACCP): The ACCP guidelines (McCool and Rosen, 2006) recommended PEP over conventional chest physiotherapy for the treatment of cystic fibrosis, stating that PEP is effective, inexpensive, safe, and can be self-administered. They also recommended devices designed to oscillate gas into the airway either directly or by chest wall compression. Mechanical insufflation-exsufflation was recommended for patients with neuromuscular disease who had an impaired cough.

Cystic Fibrosis Foundation (CFF): A CFF committee (Flume et al., 2009) conducted a systematic review of the evidence for airway clearance therapies (ACTs) for the treatment of cystic fibrosis. The techniques evaluated included: percussion and postural drainage, positive expiratory pressure (PEP), active-cycle-of-breathing technique (ACBT), autogenic drainage, oscillatory PEP, high-frequency chest compression and exercise. Twenty studies met inclusion criteria. The Committee concluded that even though there was a paucity of controlled trials that assessed the long-term effects of ACTs and were powered to adequately compare therapies, the overall quality of evidence was “fair” and the benefit was “moderate”. Based on the available evidence, no ACT was demonstrated as superior to the others. The committee recommended that ACTs be performed on a regular basis in patients with CF and the kind of ACT used should be based on the individual needs of the patient.

Use Outside of the US
Airway clearance devices are approved and available worldwide. For example, PARI Respiratory Equipment, Inc. distributes various devices in Germany, Russia, Japan, China and the United Kingdom.

The British Thoracic Society’s (BTS) 2012 (reaffirmed 2016) guideline for the respiratory management of children with neuromuscular weakness included use of airway assist devices. In children with loss of bulbar function or those who cannot perform manual cough assist or air-stacking or in whom these techniques are ineffective, mechanical insufflation/exsufflation (MI-E) “should be considered”. BTS also stated that oscillatory techniques (e.g., HFCWS and IPV) “should be considered” in children who have difficulty mobilizing secretion or have persistent atelectasis nonresponse of other techniques of airway clearance. These recommendations were based on non-randomized controlled trials.

National Institute for Health and Clinical Excellence (NICE): In guidelines on the management of chronic obstructive pulmonary disease, NICE (United Kingdom) (2010) recommended that PEP masks be used by patients who have excessive sputum and to be considered for selected patients with exacerbation of COPD to aid in clearing sputum.

Ontario Health Technology (OHT): Following a systematic review of the literature that included thirteen randomized controlled trials, the Ontario Health Technology Advisory Committee (2009) recommendations for airway clearance devices for cystic fibrosis stated that positive expiratory pressure devices could be considered as an alternative to conventional physiotherapy. These devices are at least as effective as physiotherapy, are
safe, inexpensive, and can be self-administered. Airway oscillation devices are an alternative therapy for cystic fibrosis patients when positive expiratory pressure devices are ineffective, contraindicated, or intolerable. However, OHT did not recommend the use of high-frequency chest wall compression (HFCWC) devices as an alternative to conventional physiotherapy for the treatment of cystic fibrosis because of the low quality of the evidence comparing their effectiveness to physiotherapy and the excessive cost of the devices.

## Coding/Billing Information

**Note:**
1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

### Mechanical Percussors, Positive Expiratory Pressure Devices, Oscillatory Positive Expiratory Pressure Devices

Considered medically necessary when criteria in the applicable policy statements listed above are met:

<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>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>
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<tr>
<td>S8185</td>
<td>Flutter device</td>
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### Mechanical Insufflation-Exsufflation Devices

Considered medically necessary when criteria in the applicable policy statements listed above are met:

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>E0482</td>
<td>Cough stimulating device, alternating positive and negative airway pressure</td>
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### High-Frequency Chest Wall Compression Device

Considered medically necessary when criteria in the applicable policy statements listed above are met:

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>E0483</td>
<td>High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
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</table>

## Acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination device

Considered medically necessary when used to report Vibralung®:

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<th>Description</th>
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<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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Intrapulmonary Percussive Ventilation Device

Considered Experimental/Investigational/Unproven:

<table>
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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and related accessories</td>
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</tbody>
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References


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