CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Airway Clearance Devices in the Ambulatory Setting**

Effective Date 9/15/2008
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Coverage Policy Number 0069

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Lung Transplantation
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INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2008 CIGNA*

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.

CIGNA covers ANY of the following types of airway clearance devices as medically necessary for patients with diagnoses that are characterized by excessive mucus production and difficulty clearing secretions:

- mechanical percussors
- positive expiratory pressure devices
- vibratory positive expiratory pressure devices

CIGNA covers mechanical insufflation-exsufflation devices as medically necessary for patients with neuromuscular disorders with significant impairment of chest wall and/or diaphragmatic movement resulting in difficulty clearing secretions.

CIGNA covers high-frequency chest wall compression devices as 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 to mobilize secretions

CIGNA does not cover intrapulmonary percussive ventilation devices for home use because they are considered experimental, investigational or unproven.

General Background

Respiratory disorders characterized by excessive respiratory secretions and impaired airway clearance include cystic fibrosis (CF), chronic bronchitis, emphysema with a chronic bronchitic component, chronic asthma, dyskinetic cilia syndromes, diffuse panbronchiolitis, and idiopathic bronchiectasis. Neuromuscular diseases (NMD), 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 clear mucus from the airways effectively. Mechanically-ventilated patients may lack the ability to mobilize and clear respiratory secretions without support. Secretions that plug the airway can result in atelectasis (i.e., partial or complete collapse of the lung) and decreased oxygenation (Aldrich, 2000; Donahue, 2002).

Cystic fibrosis is the major cause of severe chronic lung disease in children and is characterized chiefly by obstruction and infection of airways. CF produces thick, sticky mucus that clogs airways and breathing passages. As a result, persistent coughing with expulsion of mucus or phlegm, wheezing, shortness of breath, and recurrent respiratory infections are commonly associated with CF. 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. Airway clearance techniques (ACT) can be critical to the management of the CF patient. Bradley et al. (2006) recorded the results of five Cochrane reviews addressing physical therapies (i.e., airway clearance and physical training) utilized in the treatment of CF. The multiple randomized studies included in the Cochrane reviews included the outcomes of treatments with a wide range of these therapies (e.g., coughing, manual and acoustic chest percussion, postural drainage, exercise, positive expiratory pressure [PEP], flutter, active cycle of breathing techniques, mechanical percussion, and high-frequency chest compression). The reviewers concluded that no definitive evidence was available, but widespread consensus indicated that airway clearance is essential to the successful treatment of CF “to promote mucociliary clearance by altering airflow and mucus viscosity.” They also stated that the reviews did provide some evidence to support the use of physical therapies and no evidence to discourage their use. Main et al. (2005) also conducted a literature review of randomized and quasi-randomized studies comparing the use of conventional CPT with other airway clearance techniques (i.e., HFCWC, MP, acoustic percussion, forced expiration techniques, airway oscillation devices, autogenic drainage, exercise with CPT, and PEP) in CF patients. The authors concluded that there were no differences between CPT and other techniques in regards to respiratory function. However, there were “relatively” large gains in respiratory function during acute exacerbations irregardless of technique utilized and there was some evidence of preference for self-administered techniques.

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. Treatment with antibiotics and efforts at improved pulmonary clearance allow some control of disease progression, but rarely eradicates the infections completely and do not reverse the anatomical changes significantly (Morrissey, 2004). CF is the most common cause of childhood bronchiectasis in North America. Bronchiectasis can also follow severe pneumonia, retained foreign body, hydrocarbon aspiration, or primary ciliary dyskinesia syndromes. Treatment consists of chest physiotherapy (CPT), antibiotics and other maneuvers designed to mobilize secretions (Irwin, 1998).

The muscular dystrophies (MD) are a group of genetic diseases characterized by progressive weakness and degeneration of the skeletal muscles that control movement. The three most common types of MD are Duchenne, facioscapulohumeral, and myotonic. MD varies in age of onset, presenting symptoms, rate of progression and distribution of weakness. The symptoms of MD vary with the type of disease. Symptoms include: muscle weakness, hypotonia, ptosis, drooling, impaired ability to ambulate, joint contractures, scoliosis, and mental retardation. Treatment of MD is supportive, based upon presenting symptoms and problems at any given point in the course of the disease, and may include: physical therapy, respiratory therapy, pharmacotherapy and orthopedic interventions for prevention, support, and treatment of contractures. Because of weakened muscles, MD patients may develop respiratory difficulties leading to excess phlegm, inability to cough and resulting infections. ACTs are especially helpful to these patients as well.

The standard of care for ineffective mucus clearance from the airways is postural drainage therapy (PDT), also commonly referred to as chest physical therapy (CPT), postural drainage and percussion, and percussion and vibration. PDT uses postural drainage, percussion, vibration, deep breathing and coughing to loosen and move secretions out of the lungs in an attempt to normalize functional residual capacity. Additional therapies may include nutritional support, antibiotic therapy, mucolytic agents, bronchodilators, anti-inflammatory agents, chronic suppressive antibiotic therapy, corticosteroids and supplemental oxygen (Boucher, 2000; Yeates, 2000; Wagener, 2003; Yankaskas, 2004).

Contraindications for PDT include: situations in which there is head, neck, chest or back instability and/or injuries; anatomical deformities; severe spasticity; mental limitations; or the patient cannot tolerate the position for other reasons.

ACTs are treatments that loosen thick, sticky lung mucus so it can be cleared by coughing or huffing and may be indicated if PDT is ineffective, cannot be tolerated or is contraindicated. Clearing the airways reduces lung infections and improves lung function. In addition to PDT, other types of ACTs include: coughing, huffing, percussion, active cycle of breathing technique (ACBT), autogenic drainage (AD), positive expiratory pressure (PEP) therapy, oscillating positive expiratory pressure (oscillating PEP), and high-frequency chest wall compression (HFCWC). ACTs and devices may be used alone or in conjunction with pharmacotherapy agents, such as bronchodilators and antibiotics.

Compliance with airway clearance programs is essential for maximal clinical outcomes. Factors that influence patient adherence to an airway clearance program include the patient's ability to learn, motivation, preference and resources. Because conventional CPT requires assistance during administration, patients in the home setting may be less likely to comply due to reluctance to request assistance or due to the unavailability of assistance. Patients can perform CPT independently in the home setting with assistance of airway clearance devices and, therefore, are more likely to comply with treatment (Oermann, et al., 2001; Yankaskas, 2004).

Mechanical Percussion

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 are currently considered a standard of care in airway clearance therapy.

Percussors are classified as Class II 510 (k) medical devices by the U.S. Food and Drug Administration (FDA). The Fluid Flo Model 2500 Percussor (MED SYSTEMS, San Diego, CA) and the Frequencer™ (Dymedso Inc., Canada) are examples of mechanical percussors.

Cantin et al. (2006) studied the effectiveness of the Frequencer in clearing secretions from the airway in 22 CF patients. Sputum production following the use of the Frequencer was compared to sputum production following conventional clapping and postural drainage (CCPT). Each therapy was administered for 20 minutes. Patients received both types of therapy in one session. Each session was separated by a 12–24 hour period. In the following session, the sequence of the therapies was switched so that the first therapy administered each time was different. The weight of the sputum was comparable following each session in both groups.

The American Association of Respiratory Care (AARC) (1991) guideline on postural drainage therapy includes the use of external manipulation of the thorax as a component of bronchial hygiene therapy. According to the guideline, external manipulation is indicated when "sputum volume or consistency suggests that there is a need for additional manipulation to assist movement of secretions by gravity, in a patient receiving postural drainage." AARC stated that there was no conclusive evidence that supported the superiority of either manual or mechanical methods.

Summary: Mechanical percussors are considered standard of care as an airway clearance techniques and are as effective as manual percussion. The devices may be used alone or in conjunction with manual techniques.

Positive Expiratory Pressure
Expiratory resistance or positive expiratory pressure (PEP) devices promote mucus clearance by preventing airway closure and increasing collateral ventilation and are considered a standard of care for assisting in airway clearance. 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. A PEP device is used with a mask or mouthpiece and can be adapted for the concomitant delivery of bronchodilators. PEP therapy can be taught to children as young as five years and can be passively given to infants via masks. It is effective without the need for postural drainage. It is ineffective when performed incorrectly; therefore, there is a need for supervision when children are performing PEP (Shelton, 2004).

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 RC Cornet® device (Pari Respiratory Equipment, Midlothian, VA).

A systematic review of the literature (Elkins, et al., 2004) involving 429 participants reported that there was no clear evidence that PEP was more or less effective as an intervention than other forms of physiotherapy.There was some evidence that subjects preferred PEP to other airway clearance techniques. A 2007 randomized controlled trial compared the outcomes of PEP and forced expiratory technique (FET) (n=32) to FET in the treatment of chronic obstructive pulmonary diseases and reported that there was no statistically significant differences in outcomes. Both groups experienced significant increase in diffusing capacity compared to baseline.

The AARC developed a clinical practice guideline on the use of positive airway pressure adjuncts to bronchial hygiene therapy (1993). This guideline provides indications for the use of PEP therapy as an adjunct in mobilizing secretions and treating atelectasis.

In two 2006 evidence-based practice guidelines (i.e., "Diagnosis and Management of Cough Executive Summary" and "Nonpharmacologic Airway Clearance Therapies"), the American College of Chest Physicians (ACCP) advocated the use of PEP over conventional chest physiotherapy for the treatment of CF. The ACCP states that PEP is effective, inexpensive, safe and can be self-administered (Irwin, et al., 2006; McCool and Rosen, 2006).

Summary: CPT requires the reliance on a support person. PEP therapy has been shown to be as effective as CPT and may lead to greater compliance in an airway clearance program in patients who prefer this method or do not have access to CPT.

Vibratory Positive Expiratory Pressure
Another airway clearance device that is considered standard of care is the vibratory (or oscillating) 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. 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 administer via a mouthpiece (Shelton, 2004).

Examples of these Class II 510 (k) devices are the Flutter® (Scandipharm, Birmingham, AL) and the Acapella® (DHD Healthcare, Wampsville, NY). Although these two devices have similar performance characteristics, Acapella's performance is not gravity-dependent and may be easier for some patients to use (Volsko, et al., 2003).

Numerous small randomized controlled trials (n=15–36) with short-term follow-up have compared vibratory or oscillating PEP therapy (e.g., Flutter, Acapella) to CPT, 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, duration of therapy, and patient perception of therapy. Overall, oscillating PEP was considered as good as other forms of ACT (App, et al., 1998; Scherer, et al., 1998; Gondor, et al., 1999; Oermann, et al., 2001; Thompson et al., 2002; Patterson, et al., 2005; McCarren and Alison, 2006; Lagerkvist, et al., 2006; Eaton, et al., 2007; Patterson, et al., 2007).

Summary: Vibratory PEP has been shown to be as effective as CPT. It may not be as effective as PEP in patients with cystic fibrosis and is not the preferred method of treatment in CF patients. However, some patients may find this type of device preferable to PEP, and treatment compliance is a crucial aspect in managing airway clearance. According to Wagener et al. (2003), any relatively effective method that is preferred by the patient may increase participation in routine airway clearance.

High-Frequency Chest Wall Compression
When conventional PDT and other devices have failed or are contraindicated, high-frequency chest wall compression (HFCWC) may be indicated and is considered the standard of care in these circumstances. HFCWC or oscillation is a mechanical form of chest physiotherapy. This technique assists with mucociliary clearance by altering airflow patterns and reducing sputum viscosity. The system is composed of a fitted vest coupled to a pneumatic compressor. The compressor frequently 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 (Shelton, 2004; Wagener, et al., 2003).

The original device received 510(k) approval from the FDA in 1998. The Vest™ Airway Clearance System (Hill-Rom, St. Paul, MN; previously manufactured by Advanced Respiratory, St. Paul, MN) and Medpulse™ Respiratory Vest System (Electromed, Inc. Minnetonka, MN) are examples of these devices (Hayes, 2005).

The evidence in multiple studies demonstrated that HFCWC was an effective therapy for airway clearance. Randomized controlled trials (n=2–29) with up to one-year follow-up compared the use of HFCWC to CPT, 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 (Whitman, et al., 1993; Kluft, et al., 1996; Sherer, et al., 1998; Oermann, et al., 2001; Lange, et al., 2006).

A technology assessment by Hayes (2004) found HFCWC to be comparable in safety and efficacy to other physical therapies that assist in airway clearance, such as standard CPT and oscillating positive expiratory pressure (PEP). HFCWC improved lung function and sputum clearance in many CF patients, with few adverse effects. HFCWC is considered comparable to CPT in the ability to enhance sputum production. Although definitive patient selection criteria have not been established, there is sufficient evidence to support HFCWC's use in children age six years and older. It is contraindicated in patients with unstable head and neck injuries, active hemorrhage with hemodynamic instability, or history of pneumothorax, hemoptysis or cardiac arrest in the past 30 days.

Summary: Evidence in the peer-reviewed literature has demonstrated that HFCWC is a safe therapy and is at least as effective as CPT and other methods of airway clearance in patients in whom conventional PDT and other devices have failed.

Mechanical Insufflation-Exsufflation
Patients with neuromuscular weakness can have a decreased ability to mobilize and remove secretions from the airways. Inspiratory muscle weakness limits the depth of the pre-cough inspiration; bulbar weakness or presence of a tracheostomy impairs glottic closure; and expiratory muscle weakness or distortion of the chest wall from scoliosis can reduce intrathoracic expiratory pressure and flows (Aldrich, 2000).

Mechanical insufflator-exsufflators (MI-Es) are portable electric devices that alternately apply positive and rapid negative pressure to a patient’s airway and are considered a standard of care device for use 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, thus simulating a 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 to/from the patient via a breathing circuit incorporating a flexible tube, a bacterial filter, and either a facemask or mouthpiece. Mechanical insufflation-exsufflation therapy can be provided in the home with assistance from a family member or health professional (Hayes, 2003).

Randomized (Chatwin, et al., 2003) and nonrandomized trials (Bach, et al., 1993; Bach, 1993; Sancho, et al., 2004; Miske, et al., 2004; Winck, et al., 2004) (n=26–62) have compared the use of MI-E to CPT, manual coughing, and noninvasive ventilation, as well as evaluated the use of MI-E alone . Outcomes revealed that MI-E was as effective as other methods of ACT. Decreased breathlessness, and improved oxygenation, pulmonary function values, sputum production, and peak flow cough were reported. One study reported that MI-E was well tolerated by 90% of the patients (Miske, et al., 2004).

In a Health Technology Brief, Hayes concluded that the data found in the available studies does not “provide convincing evidence” that the use of the CoughAssist MI-E device (J.H. Emerson Co., MA) results in better outcomes than standard methods of airway clearance (Hayes, 2006).

The Consensus Panel Report of the American College of Chest Physicians indicated that mechanical insufflation-exsufflation can result in a more than fourfold increase in cough expiratory flows (Irwin, et al., 1998).

The American Academy of Neurology's (AAN's) practice parameter on the care of the patient with ALS supports the use of MI-E in clearing secretions from the airway (Miller, et al., 1999).

The American Thoracic Society issued a consensus statement (Finder, et al., 2004) on respiratory care of the patient with Duchenne muscular dystrophy (DMD). The committee supports the use of MI-E for patients with DMD to clear airway secretions.

Summary: The body of evidence supports the safety and efficacy of MI-E for airway clearance in patients with neuromuscular disease.

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 or vibrations, aerosol and pressure loosen secretions, stimulates cough and leads to sputum production. Although typically utilized during hospitalization, IPPV has been proposed for in-home use.

There are multiple models manufactured by Percussionaire Corporation (Sandpoint, ID), including both institutional and home devices. Examples are the Percussionator®, TXP® Universal VENTILATOR Percussionator® and The IMPULSATOR®. According to the manufacturer, the devices create internal percussion of the lungs, which can help propel deeply retained airway secretions upward from the lungs, where they can be more easily expectorated. The percussions are delivered continuously through an accessory device called the Phasitron®.

Natale et al. (1994) conducted a pilot study consisting of a randomized crossover trial of three treatment regimens in nine nonhospitalized patients with cystic fibrosis. The treatments were IPV with active percussion, IPV with inactive percussion followed by CPT, and standard aerosol therapy followed by CPT. Outcomes demonstrated no consistent or meaningful differences in sputum properties between the three modalities. Birnkrant et al. (1996) studied four patients (three with neuromuscular disease and one with segmental atelectasis due to aspiration) who utilized IPV initially in the hospital and after discharge to home. One patient developed third-degree atrioventricular block, hypoxemia and bradycardia during the hospital treatment phase, precipitated by upper-airway obstruction by a mucus plug. The authors noted that IPV use requires close observation during and after treatments, especially in patients who have difficulty mobilizing or expectorating sputum.

Newhouse et al. (1998) compared the use of IPV and the Flutter device with manual CPT in a small pilot study of ten cystic fibrosis patients. Participants were randomized to outpatient treatment on three separate days for three successive weeks. Eight of the ten participants completed the trial; two were hospitalized for exacerbation of pulmonary infections. There was no increase in the quantity of sputum production noted between the various groups. There was a trend towards lower lung volumes with a decrease in residual volume (RV) for all three groups at one hour and for IPV and CPT at four hours.

Marks et al. (2004) reported on a pilot study of 10 patients with cystic fibrosis who utilized the PercussiveTech HF (PTHF) device (now known as PercussiveNEB™, Vortran Medical Technology 1, Sacramento, CA) for a single intervention in stable CF patients. PTHF is similar to IPV, as both devices deliver a large volume of aerosol while delivering oral high-frequency positive-pressure airway oscillation. The IPV is designed to oscillate primarily during inhalation, with exhalation remaining passive. The PTHF device oscillates during both inhalation and exhalation but is designed to cycle mainly during exhalation, maintaining airway patency. In this study, two treatment regimens were used: albuterol delivered via nebulizer followed by standard CPT, and albuterol delivered via the PTHF device without CPT. Outcome results found that there was a trend for more sputum production after PTHF compared to production after CPT, but this difference did not reach statistical significance.

Summary: The safety and efficacy of IPV treatment for home use has not been established because the devices have not been studied sufficiently in the home environment. Long-term studies are needed to assess the safety and efficacy of these devices as an alternative to CPT or other established airway clearance methods.

Professional Societies/Organizations
The Cystic Fibrosis Foundation issued a consensus report regarding adult care in cystic fibrosis. The report included the use of CPT, PEP and HFCWC in the management of airway clearance. The report notes that CPT can be physically demanding and time-consuming for both the individual and his/her support person. Poor adherence with CPT is common. As patients become older and more independent, they frequently seek other airway clearance methods which can be performed without assistance (Yankaskas, 2004).

The Cystic Fibrosis Foundation's Consumer Fact Sheet lists oscillating positive expiratory pressure devices (e.g., Flutter, Acapella, and IPV) as devices that may be used to thin, dislodge and move secretions. They also describe the use of the high-frequency chest wall oscillator or vest, as well as PEP as therapeutic alternatives (Cystic Fibrosis Foundation, 2004). They stated that the technique and device prescribed would be based upon patient condition and physician decision.

In the "Nonpharmacologic Airway Clearance Therapies: ACCP Evidence-Based Clinical Practice Guidelines," the ACCP states that the evidence supporting the use of oscillatory devices (i.e., Flutter, intrapulmonary percussive ventilation and high-frequency chest wall oscillation) in the treatment of patients with CF was low and the reported benefits were conflicting. Their recommendation was inconclusive. For the treatment of neuromuscular disease, they rated the evidence as low with an intermediate benefit and gave these devices a weak recommendation (McCool and Rosen, 2006).

Summary
Pulmonary and neuromuscular diseases associated with excess respiratory secretions and impaired airway clearance can be unresponsive to conventional physiotherapy (e.g., coughing, huffing, postural drainage, and manual chest percussion) and/or pharmacotherapy resulting in the need for assistive airway devices to help loosen secretions, enhance sputum expectoration and clear the airway. Evidence in the peer-reviewed scientific literature, as well as professional societies, support the safety and efficacy of in-home use of mechanical percussion, positive expiratory pressure (PEP) devices, vibratory positive expiratory pressure therapy, high-frequency chest wall compression and mechanical insufflation-exsufflation for airway clearance. The most effective modality will vary from individual to individual based upon their personal situation (e.g., the age of the patient, underlying disease process, home situation, etc.).

The evidence in the peer-reviewed scientific literature does not support in-home use of intrapulmonary percussive ventilation as a safe and effective airway clearance technique. The studies involved small patient populations; were short-term and inconclusive; lacked standardization of therapy; and demonstrated no advantage over, or equivalency to, conventional chest physiotherapy.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS Codes	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
E0480†	Percussor, electric or pneumatic, home model
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
S8185†	Flutter device

†**Note: Coverage is limited to those specific indications outlined in the Coverage Policy section of this document.**

ICD-9-CM Diagnosis Codes	Description
277.00 – 277.09	Cystic fibrosis
335.20 – 335.29	Motor neuron disease
358.8	Other specified myoneural disorders
358.9	Unspecified myoneural disorders
359.0 – 359.1	Muscular dystrophies and other myopathies
491.20 – 491.22	Obstructive chronic bronchitis
493.20 – 493.22	Chronic obstructive asthma
494.0 – 494.1	Bronchiectasis
	Multiple/Varied

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
E0481	Intrapulmonary percussive ventilation system and related accessories

ICD-9-CM Diagnosis Codes	Description
	All codes

References

1. Aldrich TK, Rochester DF. The lungs and neuromuscular diseases. In: Murray JF, Nadel JA, Mason RJ, Boushey HA Jr, editors. Textbook of respiratory medicine. 3rd ed. Philadelphia, PA: W.B. Saunders Company; 2000. p. 2329-49.

2. American Association for Respiratory Care (AARC). Postural drainage therapy [clinical practice guideline]. Respir Care. 1991;36:1418-26. Accessed Apr 2, 2008. Available at URL address: http://www.rcjournal.com/cpgs/pdtcpg.html

3. American Association for Respiratory Care (AARC). Use of positive airway pressure adjuncts to bronchial hygiene therapy [clinical practice guideline]. Respir Care. 1993;38:516-21. Accessed Apr 2, 2008. Available at URL address: http://www.rcjournal.com/cpgs/papcpg.html

4. App E, Kieselmann R, Reinhardt D, Lindemann H, Dasgupta B, King M, et al. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: Flutter vs. autogenic drainage. Chest. 1998 Jul;114(1):171-7.

5. Arens R, Gozal D, Omlin KJ, Vega J, Boyd KP, Keens TG. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. Am J Respir Crit Care Med. 1994;150:1154-7.

6. Bach JR. Mechanical insufflation-exsufflation: comparison of peak expiratory flows with manually assisted and unassisted coughing techniques. Chest. 1993 Nov;104(5):1553-62.

7. Bach JR, Smith WH, Michaels J, Saporito L, Alba AS, Dayal R, et al. Airway secretion clearance by mechanical exsufflation for post-poliomyelitis ventilator-assisted individuals. Arch Phys Med Rehabil. 1993 Feb;74(2):170-7.

8. Birnkrant DJ, Pope JF, Lewarski J, Stegmaier J, Besunder JB. Persistent pulmonary consolidation treated with intrapulmonary percussive ventilation: a preliminary report. Pediatr Pulmonol. 1996 Apr;21(4):246-9.

9. Boat TF. Cystic fibrosis. In: Behrman RE, Kliegman RM, Jenson HB, editors. Nelson textbook of pediatrics. 17th ed. Philadelphia, PA: W.B. Saunders Company; 2004. p. 1437-50.

10. Boucher RC, Knowles MR, Yankaskas JR. Cystic fibrosis. In: Murray JF, Nadel JA, Mason RJ, Boushey HA Jr, editors. Textbook of respiratory medicine. 3rd ed. Philadelphia, PA: W.B. Saunders Company; 2000. p. 308-9.

11. Bradley JM, Moran FM, Elborn JS. Evidence for physical therapies (airway clearance and physical training) in cystic fibrosis: an overview of five Cochrane systematic reviews. Respir Med. 2006 Feb;100(2):191-201.

12. California Thoracic Society. Position paper. Airway clearance devices: limited evidence for what is 'the best method'. May 25, 2006. Accessed Apr 2, 2008. Available at URL address: http://www.thoracic.org/sections/chapters/thoracic-society-chapters/ca/publications/resources/respiratory-disease-adults/AirwayClearanceDevices.pdf

13. Cantin AM, Bacon M, Berthiaume Y. Mechanical airway clearance using the frequencer electro-acoustical transducer in cystic fibrosis. Clin Invest Med. 2006 Jun;29(3):159-65.

14. Chaisson KM, Walsh S, Simmons Z, Vender RL. A clinical pilot study: high frequency chest wall oscillation airway clearance in patients with amyotrophic lateral sclerosis. Amyotroph Lateral Scler. 2006 Jun;7(2):107-11.

15. Chatburn RL High-frequency assisted airway clearance. Respir Care. 2007 Sep;52(9):1224-35; discussion 1235-7.

16. Chatwin M, Ross E, Hart N, Nickol AH, Polkey Mi, Simonds AK. Cough augmentation with mechanical insufflation/exsufflation in patients with neuromuscular weakness. Eur Respir J. 2003 Mar;21(3):502-8.

17. Cystic Fibrosis Foundation. Airway clearance techniques. 2004. Accessed Apr 2, 2008. Available at URL address: http://www.cff.org/treatments/Therapies/Respiratory/AirwayClearance/

18. Cystic Fibrosis Foundation. Consumer fact sheet. An introduction to postural drainage & percussion. 2005. Accessed Apr 2, 2008. Available at URL address: http://www.cff.org/UploadedFiles/treatments/Therapies/Respiratory/PosturalDrainage/An%20Introduction%20to%20Postural%20Drainage%20and%20Percussion%201%2D2006%2Epdf

19. Darbee JC, Ohtake PJ, Grant BJ, Cerny FJ. Physiologic evidence for the efficacy of positive expiratory pressure as an airway clearance technique in patients with cystic fibrosis. Phys Ther. 2004;84:524-37.

20. Deakins K, Chatburn RL. A comparison of intrapulmonary percussive ventilation and conventional chest physiotherapy for the treatment of atelectasis in the pediatric patient. Respir Care. 2002;47(10):1162-7.

21. De Boeck K, Vermeulen F, Vreys M, Moens M, Proesmans M. Airway clearance techniques to treat acute respiratory disorders in previously healthy children: where is the evidence? Eur J Pediatr. 2008 Mar 6; [Epub ahead of print].

22. Donahue M. Spare the cough, spoil the airway: back to the basics in airway clearance. Pediatr Nurs. 2002 Mar-Apr;28(2):107-11.

23. Eaton T, Young P, Zeng I, Kolbe J. A randomized evaluation of the acute efficacy, acceptability and tolerability of flutter and active cycle of breathing with and without postural drainage in non-cystic fibrosis bronchiectasis. Chron Respir Dis. 2007;4(1):23-30.

24. Elkins M, Jones A, Schans C. Positive expiratory pressure physiotherapy for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2004;(1):CD003147. In: The Cochrane Library, Issue 1. Chichester, UK: John Wiley & Sons, Ltd. Update: 2005;2. Updated Dec 15, 2005.

25. Fauroux B, Guillemot N, Aubertin G, Nathan N, Labit A, Clément A, Lofaso F. Physiologic benefits of mechanical insufflation-exsufflation in children with neuromuscular diseases. Chest. 2008 Jan;133(1):161-8. Epub 2007 Dec 10.

26. Finder JD, Birnkrant D, Carl J, Farber HJ, Gozal D, Iannaccone ST, Kovesi T, Kravitz RM, Panitch H, Schramm C, Schroth M, Sharma G, Sievers L, Silvestri JM, Sterni L; American Thoracic Society. Respiratory care of the patient with Duchenne muscular dystrophy: ATS consensus statement. Am J Respir Crit Care Med. 2004 Aug 15;170(4):456-65.

27. Fink JB. Forced expiratory technique, directed cough, and autogenic drainage. Respir Care. 2007 Sep;52(9):1210-21; discussion 1221-3.

28. Giarraffa P, Berger KI, Chaikin AA, Axelrod FB, Davey C, Becker B. Assessing efficacy of high-frequency chest wall oscillation in patients with familial dysautonomia. Chest. 2005 Nov;128(5):3377-81

29. Gondor M, Nixon PA, Mutich R, Rebovich P, Orenstein DM. Comparison of Flutter device and chest physical therapy in the treatment of cystic fibrosis pulmonary exacerbation. Pediatr Pulmonol. 1999 Oct;28(4):255-60.

30. Goss CH. Airway clearance in cystic fibrosis. Resp Care. 2003:48(1):20-1.

31. Haas CF, Loik PS, Gay SE. Airway clearance applications in the elderly and in patients with neurologic or neuromuscular compromise. Respir Care. 2007 Oct;52(10):1362-81; discussion 1381.

32. Hayes Alert-Technology Assessment Brief™. Mechanical insufflation-exsufflation therapy for respiratory insufficiency. Lansdale, PA: HAYES, Inc.; ©2003 Winifred S. Hayes, Inc. Dec 2003.

33. HAYES Health Technology Brief™. CoughAssist® mechanical insufflation-exsufflation (MI-E) device (J. H. Emerson Co.) for respiratory insufficiency. ©2000 Winifred S. Hayes, Inc. 2006, Oct 3.

34. HAYES Medical Technology Directory™. High-frequency chest wall compression. Lansdale, PA: HAYES, Inc.; ©2000 Winifred S. Hayes, Inc. 2000 Mar 3.

35. HAYES Medical Technology Directory™. High-frequency chest wall compression for diseases other than cystic fibrosis. Lansdale, PA: HAYES, Inc.; ©2007 Winifred S. Hayes, Inc. 2005 Apr 14.

36. Hayes Search and Summary™. Mechanical Insufflation-Exsufflation (MIE) Therapy for Respiratory Insufficiency. Lansdale, PA: HAYES, Inc.; ©2007 Winifred S. Hayes, Inc. 2006 Aug 10.

37. HAYES Update Search™. CoughAssist® mechanical insufflation-exsufflation (MI-E) device (J. H. Emerson Co.) for respiratory insufficiency. ©2007 Winifred S. Hayes, Inc. 2007, Sep 28.

38. HAYES Update Search™. High-frequency chest wall compression for cystic fibrosis. Lansdale, PA: HAYES, Inc.; ©2004 Winifred S. Hayes, Inc. 2007 Jun 5.

39. HAYES Update Search™. High-frequency chest wall compression for diseases other than cystic fibrosis. Lansdale, PA: HAYES, Inc.; ©2007 Winifred S. Hayes, Inc. 2007 Apr 5

40. Homnick DN. Making airway clearance successful. Paediatr Respir Rev. 2007 Mar;8(1):40-5. Epub 2007 Mar 26.

41. Homnick DN. Mechanical insufflation-exsufflation for airway mucus clearance. Respir Care. 2007 Oct;52(10):1296-305; discussion 1306-7.

42. Homnick DN, White F, de Castro C. Comparison of effects of an intrapulmonary percussive ventilator to standard aerosol and chest physiotherapy in treatment of cystic fibrosis. Pediatr Pulmonol. 1995 Jul;20(1):50-5.

43. Irwin RS, Bouliet L, Cloutier MM, Gold PM, Ing AJ, O'Byrne P, et al. Managing cough as a defense mechanism and as a symptom: a consensus panel report of the American College of Chest Physicians (ACCP). Chest. 1998 Aug;114(Suppl)(2):133S-81S.

44. Irwin RS, Baumann MH, Bolser DC, Boulet LP, Braman SS, Brightling CE, Brown KK, Canning BJ, Chang AB, Dicpinigaitis PV, Eccles R, Glomb WB, Goldstein LB, Graham LM, Hargreave FE, Kvale PA, Lewis SZ, McCool FD, McCrory DC, Prakash UB, Pratter MR, Rosen MJ, Schulman E, Shannon JJ, Smith Hammond C, Tarlo SM; American College of Chest Physicians (ACCP). Diagnosis and management of cough executive summary: ACCP evidence-based clinical practice guidelines.Chest. 2006 Jan;129(1 Suppl):1S-23S.

45. Karlson KH. Cystic fibrosis. In: Rakel RE, Bope ET, editors. CONN'S current therapy 2005. 57th ed. St. Louis, MO: W.B. Saunders Co.; 2005. p. 260-2.

46. Kempainen RR, Williams CB, Hazelwood A, Rubin BK, Milla CE. Comparison of high-frequency chest wall oscillation with differing waveforms for airway clearance in cystic fibrosis. Chest. 2007 Oct;132(4):1227-32. Epub 2007 Sep 21.

47. Kluft J, Becker L, Castagnino M, Gaiser J, Chaney H, Fink RJ. A comparison of bronchial drainage treatments in cystic fibrosis. Pediatr Pulmonol 1996 Oct;22(4):271-4.

48. Lagerkvist AL, Sten GM, Redfors SB, Lindblad AG, Hjalmarson O. Immediate changes in blood-gas tensions during chest physiotherapy with positive expiratory pressure and oscillating positive expiratory pressure in patients with cystic fibrosis. Respir Care. 2006 Oct;51(10):1154-61.

49. Lange DJ, Lechtzin N, Davey C, David W, Heiman-Patterson T, Gelinas D, Becker B, Mitsumoto H; HFCWO Study Group. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. Neurology. 2006 Sep 26;67(6):991-7.

50. Main E, Prasad A, Schans C. Conventional chest physiotherapy compared to other airway clearance techniques for cystic fibrosis. Cochrane Database Syst Rev. 2005 Jan 25;(1):CD002011.

51. Marks JH. Airway clearance devices in cystic fibrosis. Paediatr Respir Rev. 2007 Mar;8(1):17-23. Epub 2007 Mar 21.

52. Marks JH, Hare KL, Saunders RA, Homnick DN. Pulmonary function and sputum production in patients with cystic fibrosis: a pilot study comparing the PercussiveTech HF Device and standard chest physiotherapy. Chest. 2004 Apr;125(4).

53. McCarren B, Alison JA. Physiological effects of vibration in subjects with cystic fibrosis. Eur Respir J. 2006 Jun;27(6):1204-9. Epub 2006 Feb 2.

54. McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. Chest. 2006 Jan;129(1 Suppl):250S-259S.

55. McIlwaine PM, Wong LT, Peacock D, Davidson AG. Long-term comparative trial of positive expiratory pressure versus oscillating positive expiratory pressure (flutter) physiotherapy in the treatment of cystic fibrosis. J Pediatr. 2001 Jun;138(6):845-50.

56. Med Systems. Fluid Flo. Accessed April 2, 2008. Available at URL address: http://www.medsystems.com/model2500.html

57. Miller RG, Rosenberg JA, Gelinas DF, Mitsumoto H, Newman D, Sufit R, et al. Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review). St. Paul, MN: American Academy of Neurology (AAN); 1999.

58. Miske LJ, Hickey EM, Kolb SM, Weiner DJ, Panitch HB. Use of the mechanical inexsufflator in pediatric patients with neuromuscular disease and impaired cough. Chest. 2004;125:1406-12.

59. Morrissey BM, Harper RW. Bronchiectasis: sex and gender considerations. Clin Chest Med. 2004 Jun;25(2).

60. Myers TR. Positive expiratory pressure and oscillatory positive expiratory pressure therapies. Respir Care. 2007 Oct;52(10):1308-26; discussion 1327.

61. Natale JE, Pfeifle J, Homnick DN. Comparison of intrapulmonary percussive ventilation and chest physiotherapy. Chest. 1994;105(6):1789-93.

62. National Institute of Neurological Disorders and Stokes (NINDS). NINDs muscular dystrophy information page. Feb 12, 2008. Accessed Apr 2, 2008. Available at URL address: http://www.ninds.nih.gov/disorders/md/md.htm

63. Newhouse PA, White F, Marks JH, Homnick DN. The intrapulmonary percussive ventilator and Flutter device compared to standard chest physiotherapy in patients with cystic fibrosis. Clin Pediatr. 1998 Jul;37(7):427-32.

64. Oermann CM, Sockrider MM, Giles D, Sontag MK, Accurso FJ, Castile RG. Comparison of high-frequency chest wall oscillation and oscillating positive expiratory pressure in the home management of cystic fibrosis: a pilot study. Pediatr Pulmonol. 2001 Nov;32(5):372-7.

65. Patterson JE, Bradley JM, Hewitt O, Bradbury I, Elborn JS. Airway clearance in bronchiectasis: a randomized crossover trial of active cycle of breathing techniques versus Acapella.Respiration. 2005 May-Jun;72(3):239-42.

66. Patterson JE, Hewitt O, Kent L, Bradbury I, Elborn JS, Bradley JM. Acapella versus 'usual airway clearance' during acute exacerbation in bronchiectasis: a randomized crossover trial. Chron Respir Dis. 2007;4(2):67-74.

67. Phillips GE, Pike SE, Jaffe A, Bush A. comparison of active cycle of breathing and high-frequency oscillation jacket in children with cystic fibrosis. Pediatr Pulmonol. 2004;37:71-5.

68. Reardon CC, Christiansen D, Barnett ED, Cabral HJ. Intrapulmonary percussive ventilation vs incentive spirometry for children with neuromuscular disease. Arch Pediatr Adolesc Med. 2005 Jun;159(6):526-31.

69. Respironics. CoughAssist™ In-Exsufflator. Accessed April 2, 2008. Available at URL address: http://www.jhemerson.com/

70. Sancho J, Servera E, Diaz J, Marin J. Efficacy of mechanical insufflation-exsufflation in medically stable patients with amyotrophic lateral sclerosis. Chest. 2004 Apr;125(4):1400-5.

71. Schechter MS. Airway clearance applications in infants and children. Respir Care. 2007 Oct;52(10):1382-90; discussion 1390-1.

72. Scherer TA, Barandun J, Martinez E, Wanner A, Rubin EM. Effect of high-frequency oral airway and chest wall oscillation and conventional chest physical therapy on expectoration in patients with stable cystic fibrosis. Chest. 1998 Apr;113(4):1019-27.

73. Shelton K. Airway clearance: something for everyone. The Cystic Fibrosis Center at Stanford. Cystic Fibrosis News. Accessed Apr 2, 2008. Available at URL address: http://cfcenter.stanford.edu/CFnews1.html#AirClear

74. Su CL, Chiang LL, Chiang TY, et al. Domiciliary positive expiratory pressure improves pulmonary function and exercise capacity in patients with chronic obstructive pulmonary disease. J Formos Med Assoc. 2007;106(3):204-211.

75. Thompson CS, Harrison S, Ashley J, Day K, Smith DL. Randomised crossover study of the Flutter device and the active cycle of breathing technique in non-cystic fibrosis bronchiectasis. Thorax. 2002;57:446-8.

76. Toussaint M, De Win H, Steens M, Soudon P. Effect of intrapulmonary percussive ventilation on mucus clearance in Duchenne muscular dystrophy patients: a preliminary report. Respir Care. 2003 Oct;48(10):940-7.

77. U.S. Food and Drug Administration (FDA). 510(k) summary of safety and effectiveness. Med systems electro flo percussor model 5000. jun 9, 2003.

78. Accessed April 2, 2008. Available at URL address: http://www.fda.gov/cdrh/pdf3/k031876.pdf

79. Varekojis SM, Douce FH, Flucke RL, Filbrun DA, Tice JS, McCoy KS, et al. A comparison of the therapeutic effectiveness of and preference for postural drainage and percussion, intrapulmonary percussive ventilation, and high-frequency chest wall compression in hospitalized cystic fibrosis patients. Respir Care. 2003;48(1):24-8.

80. Volsko TA, DiFiore J, Chatburn RL. Performance comparison of two oscillating positive expiratory pressure devices: Acapella versus Flutter. Respir Care. 2003 Feb;48(2):124-30.

81. Wagener JS, Headley AA. Cystic fibrosis: current trends in respiratory care. Respir Care. 2003;48(3):234-47.

82. Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. Pediatr Pulmonol. 1991;11(3):265-71.

83. Whitman J, Van Beusekom R, Olson S, Worm M, Indihar F. Preliminary evaluation of high-frequency chest compression for secretion clearance in mechanically ventilated patients. Respir Care. 1993 Oct;38(10):1081-7.

84. Winck JC, Gonçalves MR, Lourenço C, Viana P, Almeida J, Bach JR. Effects of mechanical insufflation-exsufflation on respiratory parameters for patients with chronic airway secretion encumbrance. Chest. 2004 Sep;126(3).

85. Yankaskas JR, Marshall BC, Sufian B, Simon RH, Rodman D. Cystic fibrosis adult care consensus conference report. Chest. 2004 Jan;125(1 Suppl):1S-39S.

86. Yeates DB, Mortensen J. Deposition and clearance. In: Murray JF, Nadel JA, Mason RJ, Boushey HA Jr, editors. Textbook of respiratory medicine. 3rd ed. Philadelphia, PA: W.B. Saunders Company; 2000. p. 370.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0069	Airway Clearance Devices in the Ambulatory Setting
Great-West Healthcare	5/16/2006	04.229.02	Intrapulmonary Percussive Ventilation (IPV)
	12/20/2007	07.358.01	Mechanical Insufflation-Exsufflation
	5/15/2006	00.228.03	High-Frequency Chest Compression