Chest Physiotherapy and Airway Clearance Devices

Number: 0067

(Replaces CPBs 252, 280, 333)

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

I. Aetna considers home chest physiotherapy by a respiratory therapist medically necessary upon the initial prescription of chest physiotherapy to stabilize the member and to train family members or caregivers to administer chest physiotherapy. Chest physiotherapy by a respiratory therapist is also considered medically necessary when the member’s pulmonary condition is unstable. Chest physiotherapy by a respiratory therapist is not considered medically necessary for persons whose pulmonary condition is stable, as chest physiotherapy can be competently administered at home by a family member or caregiver.

II. Aetna considers the following airway clearance devices medically necessary durable medical equipment (DME) to assist in mobilizing respiratory tract secretions for members with the conditions that are indicated below:

A. Airway oscillating devices (e.g., Flutter and Acapella) are considered medically necessary for cystic fibrosis (CF),
chronic bronchitis, bronchiectasis, immotile cilia syndrome (also known as primary ciliary dyskinesia) and asthma.

B. Mechanical percussors (e.g., Fluid Flo and Frequencer) are considered medically necessary for CF, chronic bronchitis, bronchiectasis, immotile cilia syndrome, and asthma.

C. Positive expiratory pressure (PEP) mask is considered medically necessary for CF, chronic bronchitis, immotile cilia syndrome, asthma, and chronic obstructive pulmonary disease (COPD).

III. Aetna considers high-frequency chest compression systems (e.g., the AffloVest, the Frequencer, the SmartVest, the MedPulse Respiratory Vest System, the Vest Airway Clearance System, the ABI Vest, Respin11 Bronchial Clearance System, and the InCourage Vest/System) medically necessary in lieu of chest physiotherapy for the following indications, where there is a well-documented failure of standard treatments to adequately mobilize retained secretions:

A. Bronchiectasis, confirmed by CT scan, characterized by daily productive cough for at least 6 continuous months or by frequent (i.e., more than 2 times/year) exacerbations requiring antibiotic therapy; or

B. Cystic fibrosis or immotile cilia syndrome; or

C. The member has one of the following neuromuscular disease diagnoses:

1. Acid maltase deficiency
2. Anterior horn cell diseases, including amyotrophic lateral sclerosis
3. Hereditary muscular dystrophy
4. Multiple sclerosis
5. Myotonic disorders
6. Other myopathies
7. Paralysis of the diaphragm
8. Post-polio
9. Quadriplegia regardless of underlying etiology.

D. Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy.

Aetna considers high-frequency chest compression systems experimental and investigational for other indications (e.g., alpha 1-antitrypsin deficiency, childhood atelectasis, cerebral palsy, coma, kyphosis, leukodystrophy, scoliosis, and stiff-person (stiff-man) syndrome; not an all-inclusive list) because their effectiveness for these indications has not been established.

IV. Aetna considers mechanical in-exsufflation devices medically necessary DME for persons with a neuromuscular disease (e.g., amyotrophic lateral sclerosis, congenital myopathies, inclusion body myositis, muscular dystrophy, myasthenia gravis, poliomyelitis, progressive bulbar palsy, spinal muscular atrophy, high spinal cord injury with quadriplegia) that is causing a significant impairment of chest wall and/or diaphragmatic movement and for whom standard treatments (e.g., chest percussion and postural drainage, etc.) have not been successful in adequately mobilizing retained secretions.

V. Aetna considers intrapulmonary percussive ventilators (IPV) (e.g., the Impulsator F00012) experimental and investigational for all indications (e.g., bronchiectasis, COPD, CF, neuromuscular conditions associated with retained airway secretions or atelectasis, and post-operative pulmonary complications; not an all-inclusive list) because there is insufficient evidence supporting their effectiveness.

VI. Aetna considers continuous high-frequency oscillation therapy for the treatment of secretion-induced atelectasis experimental and investigational because there is insufficient evidence supporting its effectiveness.
Background
Cystic fibrosis (CF), chronic bronchitis, bronchiectasis, immotile cilia syndrome, asthma, and some acute respiratory tract infections can lead to abnormal airway clearance or increase sputum production. Airway secretions are cleared by mucociliary clearance (MCC), in addition to other mechanisms such as cough, peristalsis, two-phase gas-liquid flow and alveolar clearance. The underlying pathology of abnormal airway clearance differs from one illness to another. Chest physiotherapy (CPT) is a treatment program that attempts to compensate for abnormal airway clearance. By removing mucopurulent secretions, it decreases airway obstruction and its consequences, such as atelectasis and hyperinflation; furthermore, physiotherapy can decrease the rate of proteolytic tissue damage by removing infected secretions. Methods to improve removal of tenacious lung secretions in patients with CF contribute to slowing the decline in respiratory function.

The standard dependent method of pulmonary care remains clapping, vibration and compression, together with postural drainage and assisted coughing. Most practitioners prescribe 20 to 30-min CPT sessions 1 to 3 times a day, depending on the severity of disease and the presence of intercurrent infection.

Respiratory therapists can teach family members or other informal caregivers to competently administer manual CPT to children and others who are incapable of doing it for themselves. The National Heart Lung and Blood Institute (1995) of the National Institutes of Health states: "Chest therapy consists of bronchial, or postural, drainage, which is done by placing the patient in a position that allows drainage of the mucus from the lungs. At the same time, the chest or back is clapped (percussed) and vibrated to dislodge the mucus and help it move out of the airways. This process is repeated over different parts of the chest and back to loosen the mucus in different areas of each lung. This procedure has to be done for children by family members but older patients can learn to do it
by themselves. Mechanical aids that help chest physical therapy are available commercially."

Different types of airway clearance devices have been developed for independent use, which require little or no assistance by others. When a competent care giver is not available to administer CPT manually, specific alternative methods may be utilized. Many of these techniques have been developed and studied using CF patients.

De Boeck and colleagues (2008) noted that airway clearance techniques are an important part of the respiratory management in children with CF, bronchiectasis and neuromuscular disease. They are also, however, frequently prescribed in previously healthy children with an acute respiratory problem with the aim to speed up recovery. These investigators reviewed the evidence behind this use of airway clearance techniques in children without underlying disease. They stated that few studies have been performed; many different techniques are available and the therapies used are often poorly specified. It is necessary to name the specific airway clearance technique used in treatment rather than to just state "chest physiotherapy," a term that is often confused with chest clapping or vibration plus postural drainage. There is little evidence that airway clearance techniques play a role in the management of children with an acute respiratory problem. Physicians routinely prescribing airway clearance techniques in previously healthy children should question their practice.

High Frequency Chest Compression Systems

A high-frequency chest wall compression device (The Vest Airway Clearance System, formerly known as the ThAIRapy Vest, ABI Vest) (Advanced Respiratory, St. Paul, MN) is an inflatable vest connected to a compressor that provides external high-frequency chest wall oscillation. The vest is connected via tubing to an air pulse delivery system. The patient then uses a foot pedal to apply pressure pulses that
cause the vest to inflate and deflate against the thorax creating an oscillatory or vibratory motion.

High-frequency chest compression devices have been shown to increase sputum production in CF patients. Cystic fibrosis is caused by abnormal chloride ion transport on the apical surface of epithelial cells in exocrine gland tissues. The abnormally composition of secretions from affected epithelial surfaces results in increased viscosity. It has been theorized that high-frequency chest compression devices are particularly effective in clearing the abnormal secretions of CF because vibratory shear forces facilitate expectoration by reducing the viscosity of these secretions, much in the same way that shaking jello causes it to become fluid. However, high-frequency chest compression vests have not been proven to be more effective than manual chest physiotherapy. It can be used in place of manual chest physiotherapy for patients with CF where manual chest physiotherapy is unavailable.

High-frequency chest wall compression devices have been promoted for use in conditions other than CF, including non-CF bronchiectasis. However, there are no adequate published controlled clinical studies of high-frequency chest compression devices for conditions other than CF. Given the unique pathophysiology of CF resulting in the abnormal composition of CF secretions, evidence of the effectiveness of high-frequency chest wall compression devices in CF can not be extrapolated to other pulmonary conditions. The Vest was cleared by the Food and Drug Administration (FDA) for a wide variety of pulmonary conditions based on a 510(k) pre-market notification; thus the manufacturer was not required to submit the type of evidence of effectiveness that would be required to support a pre-market approval (PMA) application.

In addition, there are no adequate studies comparing high-frequency chest compression to other, relatively simple and substantially less expensive devices (e.g., Flutter, Acapella) that apply high-frequency oscillation to the airway.
The American College of Chest Physicians' evidence-based clinical practice guidelines on non-pharmacologic airway clearance therapies (McCool and Rosen, 2006) recommend oscillatory devices (e.g., Flutter, IPV, and HFCWO) be considered as an alternative to chest physiotherapy only in CF patients.

The Vest is only available for purchase (it can not be rented); the air pulse delivery system (an air-pulse generator) and flexible hoses are available for rental or purchase.

There is controversy surrounding the use of high-frequency chest physiotherapy devices for indications other than CF.

Yuan and colleagues (2010) stated that airway secretions and infections are common in cerebral palsy (CP) and neuromuscular diseases. Chest physiotherapy is standard therapy but effort is substantial. High-frequency chest wall oscillation (HFCWO) is used in CF, but tolerability and safety data in cerebral palsy and neuromuscular disease are limited. These researchers performed a prospective, randomized, controlled trial of HFCWO and standard CPT in patients with neuromuscular disease or CP. Outcome measures included respiratory-related hospitalizations, antibiotic therapy, chest radiographs, and polysomnography. Caregivers were questioned regarding therapy adherence. A total of 28 participants enrolled, 23 completed (12 CPT, mean study period 5 months). No adverse outcomes were reported. Adherence to prescribed regimen was higher with HFCWO (p = 0.036). These findings suggest safety, tolerability, and better compliance with HFCWO. Improvement in airway clearance may help prevent hospitalizations. The authors noted that larger controlled trials are needed to confirm these results.

Drosman and Jones (2005) noted that, in the pediatric population, HFCWO is most widely used in children with CF, but that children with developmental disorders involving neuromuscular dysfunction also have impaired airway clearance with or without ventilatory dependence. The authors stated that "[l]arge, long-term studies are needed examining
HFCC in the patients with developmental disorders."

In an "exploratory" randomized controlled trial, Lange et al (2006) assessed changes in respiratory function in patients with amyotrophic lateral sclerosis (ALS) after using HFCWO. This was a 12-week study of HFCWO in patients with probable or definite ALS, an Amyotrophic Lateral Sclerosis Functional Rating Scale respiratory subscale score less than or equal to 11 and greater than or equal to 5, and forced vital capacity (FVC) greater than or equal to 40% predicted. A total of 46 patients were enrolled (58.0 +/- 9.8 years; 21 men, 25 women); 22 used HFCWO and 24 were untreated. Only 35 completed the trial: 19 used HFCWO and 16 untreated. Results were reported per-protocol, rather than by intention-to-treat. HFCWO users had less breathlessness (p = 0.021) and coughed more at night (p = 0.048) at 12 weeks compared to baseline. At 12 weeks, HFCWO users reported a decline in breathlessness (p = 0.048); non-users reported more noise when breathing (p = 0.027). There were no significant differences in FVC change, peak expiratory flow, capnography, oxygen saturation, fatigue, functional quality of life, or transitional dyspnea index. When patients with FVC between 40 and 70% predicted were analyzed, FVC showed a significant mean decrease in untreated patients but not in HFCWO patients; HFCWO patients had significantly less increased fatigue and breathlessness. Satisfaction with HFCWO was 79%. The authors concluded that HFCWO was well-tolerated, considered helpful by a majority of patients, and decreased symptoms of breathlessness. In patients with impaired breathing, HFCWO decreased fatigue and showed a trend toward slowing the decline of forced vital capacity. The investigators explained that the study was exploratory in nature, and was not sufficiently powered to detect significant differences in clinical outcomes such as pulmonary complications, hospitalizations or mortality.

On the other hand, Chaisson et al (2006) did not find HFCWO to be of significant help to patients with ALS. These investigators evaluated the effectiveness of HFCWO administered through the Vest Airway Clearance System when added to standard care
in preventing pulmonary complications and prolonging the time to death in patients with ALS. A total of 9 patients with a diagnosis of ALS and concurrently receiving non-invasive ventilatory support with bi-level positive airway pressure (BiPAP) were recruited from an outpatient clinic. Four patients were randomized to receive standard care and 5 patients to receive standard care plus the addition of HFCWO administered twice-daily for 15-min duration. Longitudinal assessments of oxyhemoglobin saturation, forced FVC, and adverse events were obtained until time of death. Pulmonary complications of atelectasis, pneumonia, hospitalization for a respiratory-related abnormality, and tracheostomy with mechanical ventilation were monitored throughout the study duration. No differences were observed between treatment groups in relation to the rate of decline in FVC. The addition of HFCWO airway clearance failed to improve time to death compared to standard treatment alone (340 days +/- 247 versus 470 days +/- 241; p = 0.26). The random allocation of HFCWO airway clearance to patients with ALS concomitantly receiving BiPAP failed to attain any significant clinical benefits in relation to either loss of lung function or mortality. This study does not exclude the potential benefit of HFCWO in select patients with ALS who have co-existent pulmonary diseases, pre-existent mucus-related pulmonary complications, or less severe levels of respiratory muscle weakness.

The Frequencer (Dymedso, Inc., Boisbriand, Quebec, Canada) is a device that provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. It induces oscillatory sound waves in the chest by means of an electro-acoustical transducer (referred to as the "Power Head"), which is placed externally on the user’s chest. The Power Head is connected to a frequency generator that is capable of producing frequencies between 20 and 100 Hz, and induces sound waves in the user’s chest for the purpose of loosening mucus deposits.

The Frequencer device provides airway clearance by inducing oscillatory sound waves in the chest by means of an electro-
acoustical transducer placed externally on the patient's chest. The transducer is connected to a frequency generator which is capable of producing frequencies between 20 and 100Hz. The vibrations in the patient's chest are effective in loosening mucus deposits and promoting bronchial drainage. The Frequencer consists of two parts, a control unit and a transducer. The user places the transducer on the chest. The frequency (adjustable between 20 and 100HZ) and the volume are adjusted in the control unit to create sympathetic resonance that can be felt in the lungs. According to the manufacturer, there are significant differences between other high frequency percussors and the Frequencer. Specifically: (1) other devices deliver a frequency pounding or striking action, similar to clapping, to a patient's chest to loosen mucus. The Frequencer uses a different operating principle: higher frequency acoustic waves to excite resonance in the chest. (2) Acoustic wave action makes the Frequencer appropriate patients who are: under 3 years of age; elderly and fragile; agitated; immobilized; obese; and status/post surgery.

Cantin et al (2006) stated that clearance of mucus from airways is the cornerstone of therapy for lung disease in patients with CF. These investigators described the operation of the Frequencer, a novel respiratory physiotherapy device comprised of an electro-acoustical transducer. They hypothesized that the Frequencer would be a safe and effective therapy to help clear secretions from the airways of subjects with CF. A total of 22 individuals with CF were recruited to this study comparing sputum production during conventional chest physiotherapy (CCPT) and Frequencer therapy using a cross-over design. The sputum weight was the main outcome measure. Sputum weight was found to be a reproducible measure of the efficacy of chest physiotherapy in individual patients. The Frequencer induced airway clearance in patients with CF that was equivalent to that of CCPT. Furthermore, treatment of a 4 % mucin preparation ex-vivo with the Frequencer significantly reduced the viscosity of the mucin solution as determined in a capillary rheometer. The authors concluded that these results indicated the Frequencer is safe and as effective as CCPT in
inducing airway clearance in patients with CF.

Although clinical evidence is limited, high-frequency chest wall oscillation devices have been used for lung transplant recipients who are unable to tolerate standard chest physiotherapy in the post-operative period.

The American Academy of Neurology’s practice parameter update on “The care of the patient with amyotrophic lateral sclerosis” (Miller et al, 2009) noted that “High frequency chest wall oscillation (HFCWO) is unproven for adjunctive airway secretion management”.

McIlwaine et al (2013) noted that PEP is the most commonly used method of airway clearance (AC) in Canada for patients with CF whereas, in some countries, HFCWO is the preferred form of AC. There have been no long-term studies comparing the effectiveness of HFCWO and PEP in the CF population. These investigators determined the long-term effectiveness of HFCWO compared with PEP mask therapy in the treatment of CF as measured by the number of pulmonary exacerbations (PEs). A randomized controlled study was performed in 12 CF centers in Canada. After a 2-month wash-out period, subjects were randomized to perform either HFCWO or PEP mask therapy for 1 year. A total of 107 subjects were enrolled in the study; 51 were randomized to PEP and 56 to HFCWO. There were 19 drop-outs within the study period, of which 16 occurred prior to or at the time of randomization. There were significant differences between the groups in the mean number of PEs (1.14 for PEP versus 2.0 for HFCWO) and time to first PE (220 days for PEP versus 115 days for HFCWO, p = 0.02). There was no significant difference in lung function, health-related quality of life scores or patient satisfaction scores between the 2 groups. Positive expiratory pressure mask therapy required a shorter treatment time. The authors concluded that the results of this study favored PEP and do not support the use of HFCWO as the primary form of AC in patients with CF.

Nolan and colleagues (2014) stated that there are no published
guidelines, clinical trials or case series in the management of recalcitrant atelectasis in the infants and toddlers with HFCWO. These researchers performed a retrospective case-series study of the clinical experience in the management of atelectasis with HFCWO in post-term infants and toddlers. Subjects included non-cardiac, cardiac, non-PICU and PICU patients. The HFCWO device used was the SmartVest™ 17-25cm Wrap® (Electromed®, New Prague, MN). Patients had radiographic evidence of atelectasis not responding to mucolytic therapy (either nebulized 3 % or 7 % hypertonic saline) and conventional chest physiotherapy. A total of 23 patients with 26 separate admissions with post-term ages of 2 weeks to 17 months were treated; 4 were in the PICU, the others were in general pediatrics. Atelectasis etiologies were infectious, structural, neurological, post-surgical, congenital defects of the airways and congenital heart disease with compression of bronchi. The greatest cause of atelectasis was infectious (23, 88 %), rhinovirus being the most common (9, 35 %). Other causes and co-morbid conditions were: neurologic conditions (6, 23 %), airway anomalies (6, 23 %), and cardiovascular anomalies (3, 11 %). High-frequency chest wall oscillation was well-tolerated, with only 3 patients (11 %) having documented adverse events consisting of post-tussive emesis (2, 8 %) right after initiation of HFCWO or excessive coughing (1, 4 %). A combination of 8 Hertz x 10 minutes, then 10 Hertz x 10 minutes at pressure of 15 was the best tolerated setting for the infants and toddlers with 23 (88 %) having these settings. Patients with viral infectious etiologies consistently had more rapid resolution of the atelectasis (mean of 2 days) than those with structural and/or cardiac anomalies (mean of 9 days). The authors concluded that HFCWO with a size appropriate device, combined with nebulized 3 % or 7 % saline, for post-term infants and toddlers was well-tolerated and should be considered as a tool for treating recalcitrant atelectasis. Moreover, they stated that in post-term infants and toddlers with recalcitrant atelectasis, HFCWO, with a size appropriate device, used concurrently with nebulized 3 % or 7 % saline, may be effective therapy. These investigators stated that clinical randomized trials are needed for comparing HFCWO versus
traditional chest percussive therapy in infants and toddlers for managing atelectasis.

Furthermore, and UpToDate review on “Atelectasis in children” (Finder, 2014) does not mention high-frequency chest wall oscillation as a therapeutic option.

**Mechanical Percussors**

The purpose of percussion is to apply kinetic energy to the chest wall and lung at regular intervals. Percussion is also referred to as cupping, clapping, and tapotement. It can be accomplished by rhythmically striking the thorax with a cupped hand or a mechanical device applied directly over the lung segment(s) being drained. According to the guidelines developed by American Association for Respiratory Care (AARC) on postural drainage therapy, no convincing evidence demonstrates the superiority of one method over the other; however, use of a mechanical percussor can benefit the patient by allowing for independence and greater compliance.

**Flutter and Acapella**

The Flutter (Scandipharm, Birmingham, AL) is a handheld pipe-like device with a plastic mouthpiece on one end that the patient exhales into. On the other end of the pipe, a stainless steel ball rests inside a plastic circular cone. When the patient exhales into the device, the ball rolls and moves up and down, creating an opening and closing cycle over a conical canal. The cycle repeats itself many times throughout each exhalation intending to produce oscillations of endobronchial pressure and expiratory airflow that will vibrate the airway walls and loosen mucus so that it can be easily expectorated by the patient. The Flutter device has 510(k) status with the FDA. Although the Flutter device has not been shown to significantly change respiratory assessment parameters or pulmonary function, some patients may prefer this method over other therapies.

A similar oscillatory positive airway pressure device, the
Acapella (Smiths Medical, Watford, UK), uses a counterweighted plug and magnet to create air flow oscillation. Volsko et al (2003) noted that the Acapella and Flutter have similar performance characteristics. The author noted that the Acapella's performance is not gravity-dependent (i.e., dependent on device orientation) and may be easier to use for some patients.

**Positive Expiratory Pressure (PEP)**

The PEP mask/mouthpiece contains a valve that increases resistance to expiratory airflow. The patient breathes in and out 5 to 20 times through the flow resistor, creating positive pressure in the airways during exhalation. The pressure generated can be monitored and adjusted with a manometer. Either low pressures or high pressures are prescribed. The PEP mask/mouthpiece achieves the same goal as autogenic drainage (a special breathing technique aimed at avoiding airway compression by reducing positive expiratory transthoracic pressure) by expiring against an external airflow obstruction.

Most studies on the effectiveness of PEP have been conducted in Europe and they reported short-term equivalency of PEP to other methods of airway clearance. A published review of these studies found that PEP had similar effects on sputum clearance when compared with other methods (postural drainage forced exhalatory technique). The strongest evidence of the effectiveness of PEP comes from a 1-year randomized controlled clinical trial of PEP versus conventional physiotherapy in 40 children with CF. The patients treated with PEP showed improvements in pulmonary function, whereas pulmonary function actually declined in patients treated with conventional physiotherapy. The differences between treatment groups were statistically significant for changes in FVC and FEV1.

There are numerous PEP Mask/PEP Valves on the market. Examples include: Resistex PEP Mask (Mercury Medical,

**Intrapulmonary Percussive Ventilator (IPV)**

Intrapulmonary Percussive Ventilator (IPV) (Percussionaire Corporation, Sandpoint, ID) is an aerosol machine that delivers a series of pressurized gas minibursts at rates of 100 to 225 cycles/min to the respiratory tract. Aerosolized medications can be delivered under pressure and with oscillations that vibrate the chest. In contrast to PEP and flutter, IPV allows continuous monitored positive pressure application and percussion throughout the respiratory cycle. The patient controls variables such as inspiratory time, peak pressure and delivery rates. The Percussionaire has 510(k) status with the FDA.

There is a scarcity of scientific data to support the effectiveness of IPV. A small study (n = 16) by Homnick et al (1995) found IPV as effective as standard aerosol and chest physiotherapy in preserving lung function. A study by Newhouse et al (1998) concluded that larger and longer studies of IPV compared to standard chest physiotherapy are needed to evaluate its value for independent administration of chest physiotherapy. Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting.

Reychler et al (2006) stated that IPV, frequently coupled with a nebulizer, is increasingly used as a physiotherapy technique. However, its physiological and clinical values have been poorly studied. These researchers compared lung deposition of amikacin by the nebulizer of the IPV device and that of standard jet nebulization (SJN). Amikacin was nebulized with both devices in a group of 5 healthy subjects during spontaneous breathing. The deposition of amikacin was measured by urinary monitoring. Drug output of both devices was
measured. Respiratory frequency (RF) was significantly lower when comparing the IPV device with SJN (8.2 +/- 1.6 breaths/min versus 12.6 +/- 2.5 breaths/min, p < 0.05). The total daily amount of amikacin excreted in the urine was significantly lower with IPV than with SJN (0.8 % initial dose versus 5.6 % initial dose, p < 0.001). Elimination half-life was identical with both devices. Drug output was lower with IPV than with SJN. The amount of amikacin delivered to the lung is 6-fold lower with IPV than with SJN, although a lower RF was adopted by the subjects with the IPV. The authors concluded that the IPV seems unfavorable for the nebulization of antibiotics.

Brückner (2008) stated that assisted coughing and mechanical cough aids compensate for the weak cough flow in patients with neuromuscular diseases (NMD). In cases with preserved respiratory muscles, breathing techniques and special devices (e.g., Flutter or Acapella) can be used for secretion mobilization during infections of the airways. These physiotherapeutic approaches were summarized as oscillating physiotherapy. Their mechanisms are dependent on separation of the mucus from the bronchial wall by vibration, thus facilitating mucus transport from the peripheral to the central airways. In mucoviscidosis and chronic obstructive pulmonary disease their application is established, but there is a paucity of data regarding the commitment in patients with NMD. The effective adoption of simple oscillating therapeutic interventions demands usually a sufficient force of the respiratory muscles -- exceptions are the application of the Percussionaire (i.e., IPV) or high-frequency chest wall oscillation (HFCWO). In daily practice there is evidence that patients with weak respiratory muscles are over-strained with the use of these approaches, or get exhausted. A general recommendation for the adoption of simple oscillating physiotherapeutic interventions can not be made in patients with NMD. Perhaps in the future devices such as IPV or HFCWO will prove to be more effective in patients with NMD.

The Impulsator F00012 (Percussionaire Corp, Sandpoint, ID) is
an intra-pulmonary percussive ventilator; it is a pneumatic device that delivers high-flow-rate bursts of air and aerosol to the lungs at a frequency of 200 to 300 cycles per minute. Pulsatile breaths are delivered at a peak pressure of 20 to 40 cm H2O, titrated by visualizing percussive movement of the intercostal spaces. Breaths are delivered using a mouthpiece, and the lungs percussed for 5- to 15-second intervals over a 15- to 30-min period. There is a lack of evidence regarding the effectiveness of the Impulsator F00012.

Kallet (2013) stated that mechanically ventilated patients in respiratory failure often require adjunctive therapies to address special needs such as inhaled drug delivery to alleviate airway obstruction, treat pulmonary infection, or stabilize gas exchange, or therapies that enhance pulmonary hygiene. These therapies generally are supportive in nature rather than curative. Currently, most lack high-level evidence supporting their routine use. In this overview, the author described the rationale and examined the evidence supporting adjunctive therapies during mechanical ventilation. Both mechanistic and clinical research suggests that IPV may enhance pulmonary secretion mobilization and might reverse atelectasis. However, its impact on outcomes such as ICU stay is uncertain. The most crucial issue is whether aerosolized antibiotics should be used to treat ventilator-associated pneumonia, particularly when caused by multi-drug resistant pathogens. There is encouraging evidence from several studies supporting its use, at least in individual cases of pneumonia non-responsive to systemic antibiotic therapy. Inhaled pulmonary vasodilators provide at least short-term improvement in oxygenation and may be useful in stabilizing pulmonary gas exchange in complex management situations. Small uncontrolled studies suggest aerosolized heparin with N-acetylcysteine might break down pulmonary casts and relieve airway obstruction in patients with severe inhalation injury. Similar low-level evidence suggests that heliox is effective in reducing airway pressure and improving ventilation in various forms of lower airway obstruction. These therapies generally are supportive and may facilitate patient management. However, because they have
not been shown to improve patient outcomes, it behooves clinicians to use these therapies parsimoniously and to monitor their effectiveness carefully.

Branson (2013) stated that postoperative pulmonary complications (PPCs) are common and expensive. Costs, morbidity, and mortality are higher with PPCs than with cardiac or thromboembolic complications. Preventing and treating PPCs is a major focus of respiratory therapists, using a wide variety of techniques and devices, including chest physical therapy, continuous positive airway pressure, incentive spirometry, and IPV. The scientific evidence for these techniques is lacking.

The American Association for Respiratory Care’s clinical practice guideline on “Effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients” (Strickland et al, 2013) listed intrapulmonary percussive ventilation (IPV) as one of the interventions that were considered but not recommended due to insufficient evidence.

**Mechanical Insufflation-Exsufflation**

Mechanical insufflation-exsufflation (CoughAssist, J.H. Emerson Co., Cambridge, MA) (also known as In-Exsufflator, Cofflator, cough machine) is designed to inflate the lung with positive pressure and assist cough with negative pressure; it is advocated for use in patients with NMD. The published literature on the effectiveness of mechanical insufflation-exsufflation consists of review articles, case reports, retrospective analyses, and small, uncontrolled case series. In addition, published research on mechanical insufflation-exsufflation has come from a single investigator, raising questions about the generalization of findings. A Consensus Panel Report by the American College of Chest Physicians (Irwin et al, 1998) stated that “[t]he inability of patients with respiratory muscle weakness to achieve high lung volumes is likely to contribute to cough ineffectiveness. Increasing the inhaled volume prior to cough by air-stacking positive pressure
breaths or by glossopharyngeal breathing increases cough expiratory flows by 80% in these patients. Cough efficiency may be further enhanced by the application of negative pressure to the airway for a period of 1 to 3 s. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold." The Consensus Panel Report, however, concluded that "[w]hile a variety of nonpharmacologic protussive treatment modalities may improve cough mechanics, clinical studies documenting improvement in patient morbidity and mortality are lacking."

Motivation to perform any airway clearance technique is key to maintaining pulmonary function. An increase in sputum production, while not necessarily an indicator of improved pulmonary function, motivates most patients to continue with their physiotherapy treatment. The ease in which the therapy can be performed by a particular patient is another important consideration. Most adolescent and adult patients who need chest physiotherapy are able to carry out their treatment independently with one of the above methods and using gravity assisted positions and breathing exercises. Positive expiratory pressure mask/mouthpiece and the Flutter device are well accepted by children. Long-term comparison of these methods with large groups of patients including the selection of appropriate outcome measures, are needed for further evaluation of the potential success of various methods of airway clearance.

Continuous High-Frequency Oscillation Therapy for the Treatment of Secretion-Induced Atelectasis

Morgan and colleagues (2016) noted that continuous high-frequency oscillation (CHFO) creates a pressure gradient in the small airways that accelerates expiratory flow. The intended use of CHFO therapy is to facilitate secretion removal and treat atelectasis. These researchers evaluated the feasibility, safety, and effectiveness of CHFO in the mechanically ventilated pediatric population. After institutional review board approval, these investigators retrospectively reviewed medical
records of mechanically ventilated children treated with CHFO (the MetaNeb system) at their institution from July 1, 2007 through August 31, 2012. Patients supported with extracorporeal membrane oxygenation were excluded. The authors evaluated changes in ventilator settings in subjects with ventilator data documented within 6 hours pre- and post-treatment. They evaluated arterial blood gas (ABG) results for individual treatments, comparing ABG results within 8 hours pre-therapy to ABG results within 3 hours post-treatment. Oxygen index and PaO2/FIO2 were calculated. Demographic data, blood pressure (BP), heart rate (HR), and development of new air leak while being treated with CHFO were recorded. Pre- and post-CHFO measurements were compared using Wilcoxon signed-rank testing. This cohort included 59 invasively ventilated subjects. Median age was 2 years (range of 1 month to 19 years), and median weight was 14 kg (2 to 81 kg). These researchers evaluated data on 528 total treatments (range per subject 1 to 39 treatments). Peak inspiratory pressure significantly decreased with CHFO, whereas other parameters, including PaCO2 and breathing frequency, remained stable. There was no significant change in systolic BP, diastolic BP, or HR following treatment with CHFO. One subject (2%) developed a clinically insignificant pneumothorax during CHFO. The authors concluded that CHFO is feasible and appears safe in this cohort of mechanically ventilated pediatric subjects. The rate of pneumothorax was consistent with that seen in similar pediatric ICU populations. They stated that these preliminary results suggested that CHFO may be beneficial by improving lung compliance in pediatric subjects with secretion-induced atelectasis; prospective clinical studies are needed to further evaluate the clinical safety and effectiveness of CHFO in children receiving invasive mechanical ventilation.
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

**Home Chest Physiotherapy:**

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<thead>
<tr>
<th>CPT codes covered if selection criteria are met:</th>
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<tbody>
<tr>
<td>94667, 94668</td>
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<td>94669</td>
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<td>97124</td>
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<thead>
<tr>
<th>HCPCS codes covered if selection criteria are met:</th>
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<tbody>
<tr>
<td>G0237</td>
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<tr>
<td>G0238</td>
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<table>
<thead>
<tr>
<th>ICD-10 codes covered if selection criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>E84.0 - E84.9</td>
</tr>
<tr>
<td>G12.20 - G12.29</td>
</tr>
<tr>
<td>G70.00 - G73.7</td>
</tr>
<tr>
<td>G82.20 - G82.54</td>
</tr>
<tr>
<td>J40 - J47.9</td>
</tr>
<tr>
<td>J98.6</td>
</tr>
<tr>
<td>Q33.4</td>
</tr>
<tr>
<td>Code</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Q89.3</td>
</tr>
<tr>
<td>S12.000+ - S12.9xx+</td>
</tr>
<tr>
<td>S14.101+ - S14.109+</td>
</tr>
<tr>
<td>S14.2xxS - S14.9xxS</td>
</tr>
<tr>
<td>S22.000+ - S22.089+</td>
</tr>
<tr>
<td>S24.101S - S24.109S</td>
</tr>
<tr>
<td>S24.101+ - S24.109+</td>
</tr>
<tr>
<td>S24.2xxS - S24.9xxS</td>
</tr>
<tr>
<td>S34.101S - S34.109S</td>
</tr>
<tr>
<td>S34.131S - S34.139S</td>
</tr>
<tr>
<td>S34.21xS - S34.9xxS</td>
</tr>
<tr>
<td>Z94.2</td>
</tr>
</tbody>
</table>

**Airway Clearance Devices:**

**High-frequency chest compression systems:**

**HCPCS codes covered if selection criteria are met:**

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

**ICD-10 codes covered if selection criteria are met:**

- **A15.0** Tuberculosis of lung [tuberculous bronchiectasis]
- **B91** Sequela of poliomyelitis
- **G14** Postpolio syndrome
- **E84.0 - E84.9** Cystic fibrosis
- **G12.0 - G12.9** Spinal muscular atrophy and related syndromes
- **G35** Multiple sclerosis
- **G82.20 - G82.54** Paraplegia (paraparesis) and quadriplegia (quadriparesis) [regardless of underlying etiology]
- **G71.2** Congenital myopathies
- **G71.11 - G71.19** Myotonic disorders
- **G72.0 - G72.9** Other and unspecified myopathies
- **J47.0 - J47.9** Bronchiectasis
- **J98.6** Disorders of diaphragm [paralysis of the diaphragm]
- **Q33.4** Congenital bronchiectasis
- **Q89.3** Quantitative Pupillometry/Pupillography
- **Z94.2** Lung transplant status

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

- **E71.520 - E71.529** X-linked adrenoleukodystrophy
- **E75.29** Other sphingolipidosis
- **G25.82** Stiff-Man Syndrome
- **G80.0 - G80.9** Cerebral palsy
- **J98.11** Atelectasis [childhood atelectasis]
<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M40.00 - M40.299</td>
<td>Kyphosis</td>
</tr>
<tr>
<td>M41.00 - M41.9</td>
<td>Scoliosis</td>
</tr>
<tr>
<td>P28.0</td>
<td>Primary atelectasis of newborn</td>
</tr>
<tr>
<td>P28.10 - P28.19</td>
<td>Other and unspecified atelectasis of newborn</td>
</tr>
<tr>
<td>Q67.5</td>
<td>Congenital deformity of spine</td>
</tr>
<tr>
<td>Q76.0 - Q76.419</td>
<td>Congenital malformations of spine</td>
</tr>
<tr>
<td>R40.20+ - R40.236+</td>
<td>Coma</td>
</tr>
</tbody>
</table>

**Mechanical Percussors:**

**HCPCS codes covered if selection criteria are met:**

- E0480 Percussor, electric or pneumatic, home model

**ICD-10 codes covered if selection criteria are met:**

- E84.0 - E84.9 Cystic fibrosis
- J41.0 - J42 Chronic bronchitis
- J45.20 - J45.998 Asthma
- J47.0 - J47.9 Bronchiectasis
- Q33.4 Congenital bronchiectasis
- Q89.3 Situs inversus [immotile cilia syndrome]
- Z94.2 Lung transplant status

**Flutter / Acapella Device:**

**HCPCS codes covered if selection criteria are met:**

- S8185 Flutter device

**ICD-10 codes covered if selection criteria are met:**

- E84.0 - E84.9 Cystic fibrosis
- J41.0 - J42 Chronic bronchitis
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J45.20 -</td>
<td></td>
</tr>
<tr>
<td>J45.998</td>
<td>Asthma</td>
</tr>
<tr>
<td>J47.0 - J47.9</td>
<td>Bronchiectasis</td>
</tr>
<tr>
<td>Q33.4</td>
<td>Congenital bronchiectasis</td>
</tr>
<tr>
<td>Q89.3</td>
<td>Quantitative Pupillometry/Pupillography</td>
</tr>
<tr>
<td>Z94.2</td>
<td>Lung transplant status</td>
</tr>
</tbody>
</table>

**Positive Expiratory Pressure (PEP):**

**HCPCS codes covered if selection criteria are met:**

E0484 Oscillatory positive expiratory pressure device, non-electric, any type, each

**ICD-10 codes covered if selection criteria are met:**

E84.0 - E84.9 Cystic fibrosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J40 - J47.9</td>
<td>Chronic lower respiratory diseases</td>
</tr>
<tr>
<td>Q89.3</td>
<td>Quantitative Pupillometry/Pupillography</td>
</tr>
</tbody>
</table>

**Mechanical Insufflation-Exsufflation Devices:**

**HCPCS codes covered if selection criteria are met:**

A7020 Interface for cough stimulating device, includes all components, replacement only

E0482 Cough stimulating device, alternating positive and negative airway pressure

**ICD-10 codes covered if selection criteria are met:**

A80.0 - A80.9 Acute poliomyelitis

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G12.0 - G12.1</td>
<td>Infantile spinal muscular atrophy, type I [Werdnig-Hoffman] and other inherited spinal muscular atrophy [Progressive bulbar palsy of childhood [Fazio-Londe]]</td>
</tr>
<tr>
<td>G12.20 - G12.29</td>
<td>Motor neuron disease</td>
</tr>
<tr>
<td>G12.8 - G12.9</td>
<td>Other and unspecified spinal muscular atrophies and related syndromes</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>G70.00 -</td>
<td>Myasthenia gravis</td>
</tr>
<tr>
<td>G70.01</td>
<td></td>
</tr>
<tr>
<td>G71.0</td>
<td>Muscular dystrophy</td>
</tr>
<tr>
<td>G71.2</td>
<td>Congenital myopathies</td>
</tr>
<tr>
<td>G72.41</td>
<td>Inclusion body myositis [IBM]</td>
</tr>
<tr>
<td>G82.20 -</td>
<td>Paraplegia (paraparesis) and quadriplegia</td>
</tr>
<tr>
<td>G82.54</td>
<td>(quadriparesis)</td>
</tr>
<tr>
<td>G70.00 -</td>
<td>Diseases of myoneural junction and muscle</td>
</tr>
<tr>
<td>G73.7</td>
<td></td>
</tr>
<tr>
<td>J98.6</td>
<td>Disorders of diaphragm</td>
</tr>
<tr>
<td>S12.000+ -</td>
<td>Fracture of cervical vertebra and other parts of</td>
</tr>
<tr>
<td>S12.9xx+</td>
<td>the neck</td>
</tr>
<tr>
<td>S14.0XXS -</td>
<td>Unspecified injury of cervical spinal cord,</td>
</tr>
<tr>
<td>S14.109S</td>
<td>sequela</td>
</tr>
<tr>
<td>S14.101S -</td>
<td>Unspecified injury of cervical spinal cord,</td>
</tr>
<tr>
<td>S14.109S</td>
<td>sequela</td>
</tr>
<tr>
<td>S14.101+ -</td>
<td>Unspecified injury of cervical spinal cord</td>
</tr>
<tr>
<td>S14.109+</td>
<td></td>
</tr>
<tr>
<td>S14.2xxS-</td>
<td>Injury of nerves at neck level, sequela</td>
</tr>
<tr>
<td>S14.9xxS</td>
<td></td>
</tr>
</tbody>
</table>

**Intrapulmonary percussive ventilators (IPV):**

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and</td>
</tr>
<tr>
<td></td>
<td>related accessories</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E84.0 - E84.9</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>J44.0 - J44.9</td>
<td>Chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>J47.0 - J47.9</td>
<td>Bronchiectasis</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


Manual Chest Physiotherapy:


5. Button BM, Heine RG, Catto-Smith AG, et al. Chest physiotherapy in infants with cystic fibrosis: To tip or not?


27. van der Schans CP. Conventional chest physical therapy for obstructive lung disease. Respir Care. 2007;52(9):1198-1206; discussion 1206-1209.


High Frequency Chest Compression Devices


17. Scherer TA, Barandun J, Martinez E, et al. Effect of high-frequency oral airway and chest wall oscillation and conventional chest physical therapy on expectoration in


35. Chatburn RL. High-frequency assisted airway clearance. Respir Care. 2007;52(9):1224-1237.


Intrapulmonary Percussive Ventilator (IPV)


5. Natale JE, Pfeifle J, Homnick DN. Comparison of intrapulmonary percussive ventilation and chest


Flutter and Acapella Oscillating Positive Airway Pressure Devices


14. McIlwaine PM, Wong LT, Peacock D, Davidson AG.


PEP-Mask/Valve


In-Exsufflation


Continuous High-Frequency Oscillation Therapy

AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number CPB 0067
Chest Physiotherapy and Airway Clearance Devices

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania
Updated 05/2017