Medical Coverage Policy

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Coverage Policy Number..... 0069

Airway Clearance Devices in the Ambulatory Setting

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Related Coverage Resources

Heart, Lung and Heart-Lung Transplantation

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

Coverage Policy

Coverage for Durable Medical Equipment (DME), including airway clearance devices varies across plans. Please refer to the customer's benefit plan document for coverage details.

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

ANY of the following types of airway clearance devices is considered medically necessary:

- acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination device (e.g., Vibralung®; E0480)
- mechanical percussors (HCPCS E0480)
- oscillatory (vibratory) positive expiratory pressure devices (HCPCS E0484; S8185)
- positive expiratory pressure devices (HCPCS E1399)

Mechanical Insufflation-Exsufflation Device

A mechanical insufflation-exsufflation device (HCPCS E0482) is considered medically necessary for an individual with a neuromuscular disorder (e.g., muscular dystrophy, multiple sclerosis) with significant impairment of chest wall and/or diaphragmatic movement resulting in difficulty clearing secretions.

A mechanical insufflation-exsufflation device (HCPCS E0482) for any indication not listed above is not covered or reimbursable.

High-Frequency Chest Wall Compression Device

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

- cystic fibrosis when there is failure, intolerance or contraindication to home chest physiotherapy or it cannot be provided

- bronchiectasis confirmed by high-resolution computed tomography (CT) and characterized by **BOTH** of the following:
  - daily productive cough for at least six continuous months **OR** frequent exacerbations requiring antibiotic therapy more than two times per year
  - failure of standard treatments (e.g. pharmacotherapy, postural drainage, chest percussion, vibration) to mobilize secretions
- chronic neuromuscular disease (e.g., amyotrophic lateral sclerosis, muscular dystrophy) when **BOTH** of the following criteria are met:
  - disease is characterized by excessive mucus production, infection and difficulty clearing secretions
  - failure, intolerance or contraindication to standard treatment (e.g., pharmacotherapy, postural drainage, daily chest percussion) and standard airway clearance device (e.g., mechanical percussors, positive expiratory pressure device)

A high-frequency chest wall compression device for any indication not listed above is considered not medically necessary.

Intrapulmonary Percussive Ventilation Device

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

Replacement

Replacement of an existing airway clearance device is considered medically necessary when EITHER of the following criteria are met:

- documentation confirming that the airway clearance device is malfunctioning, is no longer under warranty and cannot be repaired
- a recommendation by a health care provider that replacement due to growth or change of patient's condition is needed

General Background

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

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

According to McGarry, et al. (2017), in the past 20 years, the percentage of Hispanic patients with CF has doubled. Additionally, there is an 85% increased risk of death annually in Hispanic patients compared to non-Hispanic white patients. In a cohort study (n=15,018), McGarry, et al. found that even after controlling for factors known to impact pulmonary function, a gap exists in pulmonary function between Hispanic and non-Hispanic white patients that begins prior to six

years old when spirometry is generally first performed. Hispanic patients were found to have a 5.8% lower forced expiratory volume in one second result compared to non-Hispanic white patients. However, this gap did not appear to widen between the ages of 6 and 25 years old. The authors suggest that early exposure to environmental factors (e.g., tobacco, air pollution), poverty, language barriers, and medication non-adherence, among other contributing factors, may explain the early development of the gap in pulmonary function between Hispanic and non-Hispanic white patients.

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

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

Mechanical Percussors
Mechanical percussors are electrical devices used to provide clapping or percussion to the external chest wall. The devices deliver consistent, programmable (i.e., adjustable speed) deep pulses. The machine is moved over the patient's chest while the patient assumes a variety of drainage positions. The hand clapping performed during conventional CPT is mimicked by the machine and is less fatiguing than manual hand percussion.

U.S. Food and Drug Administration (FDA)
Percussors are approved as Class II 510(k) medical devices by the U.S. Food and Drug Administration (FDA). The Fluid Flo Model 2500 Percussor, Electro Flo® 5000 (MED Systems, San Diego, CA) and the Frequencer V2™ and Frequencer V2x™ (Dymedso Inc., Canada) are examples of mechanical percussors. Per the FDA, indications for use for the Frequencer is to provide "airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of chest physiotherapy by providing a convenient method of external thorax manipulation. It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma, muscular dystrophy, neuromuscular degenerative disorders, postoperative atelectasis and thoracic wall defects" (FDA, 2023a).

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

Positive Expiratory Pressure
Positive expiratory resistance or positive expiratory pressure (PEP) devices promote mucus clearance by preventing airway closure and increasing collateral ventilation. PEP pushes air into the lungs behind mucus, holds the airways open, and keeps them from closing. The person breathes in normally but breathes out harder against resistance. The device consists of a one-way valve connected to a small-exit orifice or an adjustable expiratory resistor. PEP therapy can be taught to children as young as age five years and can be passively given to infants via masks.

U.S. Food and Drug Administration (FDA)
PEP devices are considered Class II medical devices and are regulated by the FDA. Examples of this type of device are the TheraPEP® (DHD Healthcare, Wampsville, NY) and the Pari Pep™ device (PARI Respiratory Equipment, Inc., Midlothian, VA). TheraPEP is indicated for the treatment of patients with cystic fibrosis, lung disease with secretory problems and to prevent or reverse atelectasis. The Pari Pep device is designed to help patients exercise their lungs and improve secretion clearance. It can be used by adults or children in the home (FDA, 2023c).

Literature Review
Systematic reviews, randomized controlled trials, and case series reported that cough scores and physical activity improved following PEP. PEP was as effective as other forms of physiotherapy when patients are having difficulty clearing excessive mucus secretions (McIlwaine, et al., 2019; Lee, et al., 2017; McIIwaine, et al., 2013; Nicolini, et al., Mar 2013; Su, et al., 2007; Darbee, et al., 2004).

Oscillatory Positive Expiratory Pressure
Another airway clearance device is the oscillatory (or vibratory) positive expiratory pressure, a form of PEP that employs deep breathing and forced exhalation to achieve airway clearance via small, hand-held devices. These devices combine high-frequency air flow oscillations with PEP using a stainless steel ball or a counterweight plug and magnet to create airflow oscillations. For children as young as two years of age, vibratory PEP can be administered via a mask. For older patients (i.e., over age five) the treatment may be administered via a mouthpiece.

U.S. Food and Drug Administration (FDA)
Examples of these Class II 510(k) devices are the Flutter® (Scandipharm, Birmingham, AL), the Acapella® (DHD Healthcare, Wampsville, NY) the RC Cornet® device (Pari Respiratory Equipment, Midlothian, VA) and the AirPhysio Positive Expiratory Pressure Device (AirPhysio Pty Ltd, Ludlum, FL). The Flutter device is used to assist in the clearance of excessive secretions from the lungs of patients with cystic fibrosis, bronchitis, bronchiectasis and other diseases associated with excessive amounts of mucous. The Acapella and RC Cornet operate on the same principle as the flutter, but are not gravity dependent (FDA, 2023a; FDA, 2023c).

Literature Review
Randomized controlled trials have compared vibratory or oscillating PEP therapy (e.g., Flutter, Acapella) to chest physiotherapy, PEP, and active cycles of breathing techniques for airway clearance in patients with diseases such as cystic fibrosis, bronchiectasis, and primary ciliary dyskinesia. Reported outcomes included improvement in pulmonary function values, amount and weight of sputum, cough frequency, and duration of therapy (Bingol, et al., 2020; Lee, et al., 2015; Pryor, et al., 2010; Eaton, et al., 2007; Patterson, et al., 2007; McCarren and Alison, 2006; Lagerkvist, et al., 2006; Patterson, et al., 2005; Thompson, et al., 2002; Oermann, et al., 2001).

Mechanical Insufflation-Exsufflation
Patients with neuromuscular disorders can have significantly impaired chest wall and/or diaphragm action decreasing the ability to mobilize and remove secretions from the airways.

Mechanical insufflator-exsufflators (MI-Es), also known as cough assist therapy, are portable electric devices that alternately apply positive and rapid negative pressure to a patient's airway and are considered an established treatment option for patients with neuromuscular disorders with compromised chest wall or diaphragmatic movement. MI-Es create a rapid shift in pressure producing a high expiratory flow rate from the lungs, stimulating cough and increasing secretion clearance.

U.S. Food and Drug Administration (FDA)
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) (K002598). The CoughAssist delivers air via a breathing circuit incorporating a flexible tube, a bacterial filter, and either a facemask, mouthpiece or endotracheal or tracheostomy tube. The intended use is to "assist patients in clearing retained bronchopulmonary secretions by gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure" (FDA, 2023b). Mechanical insufflation-exsufflation therapy can be provided in the home with assistance from a family member or health professional.

Another example is the Pegaso Cough Assist (Dima Italia Srl, Boulder, CO) (K072292). The device is indicated for use "on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube." The device can be used in a hospital, institutional setting, or home use given adequate training and in both adult or pediatric patients (FDA, 2023b).

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

High-Frequency Chest Wall Compression
When conventional postural drainage therapy and other devices have failed or are contraindicated, high-frequency chest wall compression (HFCWC) may be a treatment option for patients with cystic fibrosis or bronchiectasis. HFCWC, a mechanical form of chest physiotherapy, is a system composed of a fitted vest coupled to a pneumatic compressor that uses high frequency oscillation to provide chest physiotherapy. The compressor inflates and deflates the vest, compressing and releasing the chest wall to create airflow within the lungs. The vibrations, along with the increase in airflow, help loosen mucus from the lungs. Children as young as three years of age are able to use the vest (Wagener, et al., 2003). HFCWC is an established airway clearance device for patients with cystic fibrosis who cannot tolerate chest physiotherapy or in whom chest physiotherapy is ineffective or is contraindicated. HFCWC may also be indicated for patients with chronic bronchiectasis (i.e., continuous for six months) confirmed by high-resolution computed tomography (CT) or patients with frequent exacerbations requiring antibiotic therapy who have failed conventional forms of clearing secretions. HFCWC has also evolved into an accepted airway clearance therapy for a subset of patients with neuromuscular diseases such as amyotrophic lateral sclerosis (ALS) and muscular dystrophies. For patients who have excessive mucus production, recurrent infection and difficulty clearing secretions, HFCWC can be a viable option. HFCWC is indicated when these individuals become unresponsive, cannot tolerate or there are contraindications to established therapies, such as pharmacotherapy, postural drainage and/or daily chest percussions as well as, other standard airway devices (e.g., mechanical percussors, positive expiratory pressure device).

U.S. Food and Drug Administration (FDA)
Approved by the FDA 510(k) class II process, these devices include the Vest™ Airway Clearance System (Hill-Rom, St. Paul, MN; previously manufactured by Advanced Respiratory, St. Paul, MN), the SmartVest Airway Clearance System (Electromed, Inc., New Prague, MN); inCourage System (RespirTech, Inc., St. Paul, MN), and RespIn 11 Bronchial Airway Clearance System (Respinnovations SAS, Seillans, France). The devices are approved by the FDA to promote airway clearance or improve bronchial drainage by enhancing mobilization of bronchial secretions when external manipulation of the thorax is the choice of treatment in patients who are retaining secretions and having difficulty with clearance. The Monarch® Airway Clearance System (Hill-Rom Services, Singapore) was approved by the FDA to "promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging". The Monarch is intended for home use and for patients age 15 years and older (FDA, 2023a).

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

Although there is a paucity of evidence, HFCWC has evolved into a standard of care for a subset of patients with neuromuscular diseases such as amyotrophic lateral sclerosis (ALS), muscular dystrophies, and cerebral palsy. Small randomized controlled trials (n=9-46) with short-term follow-ups have reported improvement in respiratory symptoms and quality of life scores, fewer hospital admission and hospital days, and improved adherence to treatment regimens (Fitzgerald, et al., 2014; Hayes 2014; reviewed 2018; Yuan, et al., 2010; Chaisson, et al., 2006; Lange, et al., 2006).

Some studies have investigated HFCW for other conditions. In a 2014 directory report (reviewed 2018), a Hayes systematic review of the literature investigated HFCW for non-CF conditions (e.g., COPD, asthma, postoperative care, lung cancer). Systematic reviews, randomized controlled trials and prospective case studies met inclusion criteria. The studies included small patient populations, various comparators (e.g., chest physiotherapy, usual care, sham), short-term follow-ups and conflicting outcomes. Hayes concluded that based on low quality evidence HFCWC may be beneficial to disorders of airway clearance for these other conditions, but patient selection criteria have not been established. Data on safety and effectiveness in children is lacking. Annual reviews of the literature have revealed no new data to support use of HFCW in these other conditions.

Acoustical Percussor, Positive Expiratory Pressure and Aerosol Drug Delivery System Combination Device
Vibralung® (Westmed Inc., Tucson, AZ) is an example of a combination device that can be used as an acoustical percussor and a positive expiratory pressure device and, when needed, an aerosol drug delivery system. Vibralung is also referred to as an electro-mechanical acoustical airway clearance (EMAAC) device. The device includes a handheld transducer (HHT) with a variable expiratory resistor attached to a mouthpiece. The HHT is connected to the electronic frequency generator, called the treatment control unit (TCU). When turned on, the device creates sound waves to cause vibrations/percussions in the airways to loosen and mobilize secretions. The

patient can select the intensity of the treatment by adjusting the dials on the TCU. The variable expiratory resistor (VER) provides PEP with oscillation. The orifice can be adjusted by the patient to provide minimum to maximum PEP. Vibralung can be interfaced with Westmed's Circulair II Hybrid aerosol drug delivery system to deliver medications during the treatment. Because Vibralung does not make contact with the chest wall, it is proposed that it may be gentler than oscillatory PEP devices and devices that do make chest wall contact. Therefore, Vibralung is proposed for use in conditions where other standard airway clearance devices (e.g., mechanical percussors, positive expiratory pressure device, oscillatory device, high-frequency chest wall compression device) fail to produce the necessary clinical outcome, are contraindicated or cannot be used because of chest injuries such as fractured ribs, burns or acute surgical wounds (Vibralung Acoustical Percussor, 2023).

U.S. Food and Drug Administration (FDA)
Vibralung is FDA 510(k) approved as an electric powered percussor and a predicate device to the Frequencer, Acapella and Lung Flute (Medical Acoustics, LLC, Buffalo, NY). The device is indicated as an airway secretion clearance device that creates vibrations and as a lung expansion device that applies positive expiratory pressure (PEP) as the patient breaths through the device. It may be used simultaneously with its aerosol drug delivery system. Patients with cystic fibrosis, COPD, asthma, lung diseases with secretory problems, and neuromuscular disease affecting the ability to effectively cough may be a candidate for the device (FDA, 2023a).

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

Intrapulmonary Percussive Ventilation
Intrapulmonary percussive ventilation (IPV) is a modified method of intermittent positive-pressure breathing, with superimposed high-frequency mini-bursts of air or oxygen into the lungs while simultaneously delivering therapeutic aerosols. The combination of vibrations, aerosol, and pressure loosens secretions, stimulates cough, and leads to sputum production. Although typically utilized during hospitalization, IPPV is designed for hospital use but has been proposed for in-home use.

U.S. Food and Drug Administration (FDA)
IPVs are approved by the FDA 510(k) process. There are multiple institutional and home device IPVs manufactured by Percussionaire Corporation (Sandpoint, ID), including the HC Impulsator®. Another example of an IPV device is the Volara System, also known as the Maximus System (Hill-Rom, Singapore, SG). According to the FDA approval issued in February of 2020, this device is indicated for use in mobilization of pulmonary secretions, lung expansion, and the treatment and prevention of atelectasis through the use of continuous positive expiratory pressure, continuous high frequency oscillation, and aerosolized medication. The device differs from its predicate device, MetaNeb, in that it is capable of providing higher oscillation pressures up to 50 cm H2O, the use of an electronic power source, a digital manometer, electronic pressure control, the availability of pre-programmed therapies, and the ability to use the device in the home setting (FDA, 2023b).

Literature Review
There is a paucity of evidence supporting the safety and efficacy of IPVs for home use. Studies are primarily in the form of case reports or case series with small patient populations and short-term

follow-up (Marks, et al., 2004). Some studies reported no statistically significant differences in outcomes with IPV devices.

Nicolini et al. (2018) reported on a four week, single center randomized control trial to compare the effectiveness of intrapulmonary percussive ventilation (IPV) and high-frequency chest wall oscillation (HFCWO) in patients with chronic obstructive pulmonary disease (COPD) (n=60).The third arm of the study was a control group who received "the best medical therapy". Inclusion criteria were: age > 35 years, chronic bronchitis and airway obstruction on spirometry, bronchial hypersecretion (daily sputum > 20 mL for at least two consecutive days), and effective cough (peak expiratory cough flow > 360 L/min). Exclusion criteria were the following: exacerbation of COPD or hospitalization for COPD within eight weeks prior to recruitment, history of bronchial asthma, predominant bronchiectasis, presence of tracheostomy, mechanical ventilation, recent pneumothorax, severe abnormalities of sensory, severe cardiac arrhythmias, hemodynamic instability, and chest radiograph changes. IPV treatments were administered twice a day for fifteen minutes and HFCWO was administered twice a day for 20 minutes. Treatments continued for two weeks. Patients were evaluated one week prior to start of the study and one week after completion. Primary outcomes measured were changes in dyspnea, quality of life, daily life activity and healthy status assessment as measured by the Modified Medical Research Council (mMRC) Dyspnea Scale, Breathlessness, Cough and Sputum Scale (BCSS) and the COPD Assessment Test (CAT). The secondary outcomes included changes in respiratory function testing, hematological tests, and sputum cell count. Compared to the control group, the IPV group and the HFCWO group showed significant improvements in the test of dyspnea (mMRC $p=0.001$, $p=0.004$, respectively), cough and sputum (BCSS $p<0.001$, $p=0.007$, respectively), daily life activity and healthy status assessment (CAT $p<0.001$, each). Compared to HFCWO, IPV showed a significant improvement in BCSS ($p<0.001$), CAT ($p<0.02$), total lung capacity (TLC) and TLC% ($p<0.03$), residual volume (RV) and RV% ($p<0.04$), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal expiratory pressure (MEP) ($p<0.01$, each). A significant change in neutrophil count was observed in the IPV group compared to HFCWO group ($p<0.05$). Measurement of patient acceptability was completed by questionnaire and both techniques received similar rankings. The study limitations include a small patient population, two-week treatment period, one week of follow up, and completion in a single center. Another limitation was "the best medical therapy" was not defined. The authors noted that this is the first study that investigated sputum cellularity in COPD patients. Additional randomized control trials with large patient populations and long term follow ups are needed to confirm these findings and establish the effectiveness of IPV in the treatment of COPD.

Reychler et al. (2018) conducted a systematic review of the literature to evaluate the physiological and clinical effectiveness of IPV for the treatment of acute or chronic obstructive airway diseases. Randomized controlled studies (RCTs), cohort/case studies, or comparative studies were included if they evaluated immediate or prolonged primary outcome measures of physiological effects (e.g., blood gas results, cardiorespiratory parameters, lung function, sputum weight) or secondary outcomes of the clinical effects on chronic obstructive airway diseases (COPD, cystic fibrosis [CF], asthma, or bronchiectasis. Twelve studies (n=278) including seven randomized controlled trials met the inclusion criteria. The studies investigated IPV for the treatment of COPD (n=6 studies), cystic fibrosis (CF) (n=4 studies) and bronchiectasis (n=2 study). Studies were excluded if they investigated children age < 5 years, restrictive disease or if IPV was used out of the scope of airway clearance techniques. Six different airway clearance techniques were used as a comparator and some comparators were not recognized airway clearance techniques. Few adverse events were reported. Due to the limited number of studies, small patient populations and heterogeneity of the studies (e.g., treatment regimens, comparators, outcome measures) this systematic review concluded that IPV provided insufficient and heterogeneous results and could not be recommended for routine use for the treatment of these conditions. It was noted that during COPD exacerbation (n=42; 2 studies), IPV may improve gas exchange and reduce hospital length

of stay but additional homogenous randomized controlled trials with large patient populations are needed to validate this finding.

Professional Societies/Organizations
American Academy of Neurology (AAN): In their practice parameters on the care of patients with amyotrophic lateral sclerosis (2009; reaffirmed 2020), AAN recommendations included MI-E to aid in clearing secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection.

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

In their clinical practice guideline on the respiratory management of patients with neuromuscular weakness, the ACCP provided the following conditional recommendations based on very low-quality evidence for the use of airway clearance devices:

- "For patients with NMD and reduced cough effectiveness, which cannot be adequately improved with alternative techniques, we suggest the addition of regular mechanical insufflation-exsufflation (MI-E; cough assist device) (Conditional Recommendation, Very Low Certainty of Evidence).
- For patients with NMD and reduced cough effectiveness, which cannot be adequately improved with alternative techniques, we suggest the addition of regular mechanical insufflation-exsufflation (MI-E; cough assist device) (Conditional Recommendation, Very Low Certainty of Evidence)."

The ACCP added that "higher-quality research is likely to have an important impact on our confidence in the estimate of effect" (Khan, et al., 2023).

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

In a 2016 clinical practice guideline on the management of Cystic Fibrosis in preschoolers, the CFF gave a consensus recommendation for the use of daily ACTs to improve lung function and reduce exacerbations. The CFF also gave a consensus recommendation to increase the frequency and/or duration of ACT for children diagnosed with a pulmonary exacerbation. The CFF did not give specific recommendations for the type of ACT or device used (Lahiri, et al., 2016).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Intrapulmonary percussive ventilator (IPV) (240.5)	1997
NCD	National	Durable Medical Equipment Reference List (280.1)	5/16/2023
LCD	Noridian	High frequency chest wall oscillation devices (L33785)	10/1/2022
LCD	Noridian	Intrapulmonary percussive ventilation system (L33786)	1/1/2020
LCD	Noridian	Mechanical in-exsufflation devices (L33795)	1/1/2020

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

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

Combination Devices (e.g.,Vibralung®), Mechanical Percussors, Positive Expiratory Pressure Devices, Oscillatory Positive Expiratory Pressure Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0480	Percussor, electric or pneumatic, home model
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E1399	Durable medical equipment, miscellaneous
S8185	Flutter device

Mechanical Insufflation-Exsufflation Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0482	Cough stimulating device, alternating positive and negative airway pressure

ICD-10-CM Diagnosis Codes	Description
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]

ICD-10-CM Diagnosis Codes	Description
G12.1	Other inherited spinal muscular atrophy
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Postpolio syndrome
G31.80	Leukodystrophy, unspecified (Code effective 10/01/2023)
G31.81	Alpers disease
G31.82	Leigh's disease
G31.83	Neurocognitive disorder with Lewy bodies
G31.85	Corticobasal degeneration
G31.86	Alexander disease (Code effective 10/01/2023)
G31.9	Degenerative disease of nervous system, unspecified
G35	Multiple sclerosis
G37.8	Other specified demyelinating diseases of central nervous system (Code invalid 09/30/2023) _
G37.81	Myelin oligodendrocyte glycoprotein antibody disease (Code effective 10/01/2023)
G37.89	Other specified demyelinating diseases of central nervous system (Code effective 10/01/2023)
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G70.89	Other specified myoneural disorders
G70.9	Myoneural disorder, unspecified
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.031	Autosomal dominant limb girdle muscular dystrophy
G71.032	Autosomal recessive limb girdle muscular dystrophy due to calpain-3 dysfunction
G71.033	Limb girdle muscular dystrophy due to dysferlin dysfunction
G71.0340	Limb girdle muscular dystrophy due to sarcoglycan dysfunction, unspecified
G71.0341	Limb girdle muscular dystrophy due to alpha sarcoglycan dysfunction dysfunction
G71.0342	Limb girdle muscular dystrophy due to beta sarcoglycan dysfunction
G71.0349	Limb girdle muscular dystrophy due to other sarcoglycan dysfunction
G71.035	Limb girdle muscular dystrophy due to anoctamin-5 dysfunction
G71.038	Other limb girdle muscular dystrophy
G71.039	Limb girdle muscular dystrophy, unspecified
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G71.21	Nemaline myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G72.41	Inclusion body myositis [IBM]

ICD-10-CM Diagnosis Codes	Description
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.4	Ataxic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
G90.1	Familial dysautonomia [Riley-Day]
G90.3	Multi-system degeneration of the autonomic nervous system
G91.1	Obstructive hydrocephalus
M33.21	Polymyositis with respiratory involvement
P14.2	Phrenic nerve paralysis due to birth injury
Q02	Microcephaly
Q74.3	Arthrogryposis multiplex congenita
Q93.81	Velo-cardio-facial syndrome
R53.2	Functional quadriplegia
S14.101A	Unspecified injury at C1 level of cervical spinal cord, initial encounter
S14.105S	Unspecified injury at C5 level of cervical spinal cord, sequela
S14.109A	Unspecified injury at unspecified level of cervical spinal cord, initial encounter
S14.112S	Complete lesion at C2 level of cervical spinal cord, sequela

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
	All other codes

<u>High-Frequency Chest Wall Compression Device</u>

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0483	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each

Intrapulmonary Percussive Ventilation Device

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
E0481	Intrapulmonary percussive ventilation system and related accessories

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Removed medical necessity criteria for non-managed services.	10/15/2023
Focused Review	• Updated to new template and formatting standards.	11/2/2023