MEDICAL POLICY

Excellus
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Medical Policy Title	**Airway Clearance Devices**
Policy Number	**1.01.15**
Current Effective Date	**March 16, 2026**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. High Frequency Chest Wall Compression Devices

A. High frequency chest wall compression devices (e.g., Monarch Airway Clearance System, AffloVest Vest Airway System, Smart Vest) are considered **medically appropriate** when **ALL** of the following criteria are met:

1. The patient has a documented diagnosis that impairs clearance of secretions (e.g., cystic fibrosis (CF), ciliary dyskinesia, neuromuscular disorder, or diffuse bronchiectasis);
2. The patient has a demonstrated need for the airway clearance device with exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract;
3. Documented failure of, contraindication to, or lack of available resources to administer standard treatments (e.g., pharmacotherapy, postural drainage, daily chest percussion, standard airway clearance devices such as the Flutter Valve or Acapella device.

B. Other applications of high-frequency chest wall compression devices including, but not limited to, their use as an adjunct to chest physical therapy, continuous high-frequency oscillation (e.g., Volara Oscillation and Lung Expansion System), or use in the treatment of other lung diseases such as chronic obstructive pulmonary disease (COPD) are considered **investigational**.

II. Intrapulmonary Percussive Ventilation Devices (IPV)

A. Intrapulmonary percussive ventilation devices (IPV) (e.g., Percussionaire, Percussinator IPV, TXP, Impulsator) are considered **medically appropriate** when **ALL** of the following criteria are met:

1. The patient has a documented disease that impairs clearance of secretions (e.g., cystic fibrosis (CF), ciliary dyskinesia, neuromuscular disorder, or diffuse bronchiectasis;
2. The patient has a demonstrated need for the airway clearance device with exacerbations of respiratory distress involving inability to clear mucus effectively from the respiratory tract;
3. Documented failure of, contraindication to, or lack of available resources to administer standard treatments (e.g., pharmacotherapy, postural drainage, daily chest percussion,

standard airway clearance devices such as the Flutter Valve or Acapella device).

B. Other applications of intrapulmonary percussive ventilation (IPV) devices, including, but not limited to, their use as an adjunct to chest physical therapy or use in the treatment of other lung diseases such as chronic obstructive pulmonary disease (COPD) are considered **investigational**.

III. Mechanical Insufflation-Exsufflation Devices

A. Mechanical insufflation-exsufflation devices are considered **medically appropriate**, when **ALL** of the following criteria are met:

1. The patient is diagnosed with a neuromuscular disorder, high spinal cord injury, or intrinsic lung disease that impairs chest wall and/or diaphragmatic movement;
2. The patient is unable to cough or clear secretions effectively using available manual cough assistive techniques;
3. The patient demonstrates a reduced peak cough expiratory flow (PCF), falling below 300 liters per minute (lpm);
4. The patient has no contraindications for using mechanical insufflation-exsufflation devices include but are not limited to, a history of bullous emphysema, or susceptibility to pneumothorax or pneumomediastinum (lung barotrauma injury). Patients with cardiovascular instability should be cautious when using such devices.

IV. DME Repair

A. Repair of a medically necessary airway clearance devices or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** the following:
   a. date of DME initiation;
   b. manufacturer warranty information, if applicable;
   c. attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of the DME;
2. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:
   a. inadequate function interferes with activities of daily living; and
   b. repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

V. DME Replacement

A. Replacement of a medically necessary airway clearance devices or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

1. The DME is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;
2. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

B. The replacement of a properly functioning airway clearance devices, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

C. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. Accessories or components for airway clearance devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Prior authorization and coverage for an airway clearance device is contract dependent, unless mandated by federal or state mandate.

II. Referral for an airway clearance device must be generated by a pulmonologist.

DESCRIPTION

Maintaining good bronchial hygiene in chronic pulmonary conditions (e.g., cystic fibrosis [CF], chronic bronchitis, bronchiectasis) can be a challenge in some patients. In healthy persons secretions in the lungs are moved by action of the cilia. When this clearance mechanism is ineffective in patients, such as those with weak respiratory musculature, ineffective cough or excessive tenacious secretions, chest physical therapy (also known as chest physiotherapy, CPT) becomes necessary.

The standard method of CPT is manual percussion and postural drainage. In conditions such as CF, excessive tenacious secretions necessitate routine CPT to prevent airway obstruction leading to secondary infection, which is the principal cause of morbidity and mortality. At home, manual CPT is administered to the patient by a trained adult one to three times per day for 20-30 minutes per session. Manual CPT requires assistance by another person, thereby making independent living or the

lack of a competent caregiver, a barrier to achieving the standard of care in some persons with cystic fibrosis. Daily percussion and postural drainage need to be administered by a physical therapist or another trained person. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles.

Impairment of cough and airway clearance due to muscle weakness, glottic dysfunction, and low lung volumes increases respiratory morbidity and mortality risk. Thus, airway clearance techniques (ACT) are considered a high priority for people diagnosed with a neuromuscular disease (NMD), since respiratory failure is a significant concern (Khan 2023). There are several alternative methods available to support good bronchial hygiene in persons who have chronic pulmonary conditions and who are unable to comply with a prescribed regime of pulmonary therapy.

Oscillatory Devices

Oscillatory devices are designed to move mucus and clear airways. The oscillatory component can be intra- or extra-thoracic, depending on the device. Some devices require the active participation of patients. Many of these devices require active patient participation. For example, oscillating positive expiratory pressure (OPEP) devices such as the Flutter and Acapella require the patient to exhale multiple times through the device to generate oscillations that help loosen mucus. Other airway clearance techniques also rely on structured breathing exercises performed by the patient to mobilize secretions. Autogenic drainage and active cycle breathing techniques are examples that require coordinated breathing patterns. Similarly, positive expiratory pressure (PEP) therapy involves the patient exhaling through a resistor to generate positive pressure during a prolonged exhalation, aiding in mucus clearance.

High-frequency chest wall compression (HFCWC) devices provide passive oscillatory therapy that does not require active patient participation. This mechanical form of CPT technique assists with mucociliary clearance by altering airflow patterns and reducing sputum viscosity. The system is composed of a specially equipped vest, as well as a compressor that is mechanized to provide high-frequency chest compression. The system allows frequent inflation and deflation of the vest, compressing and releasing the chest wall to create airflow within the lungs. The vibrations, along with the increased airflow help to loosen mucus from the lungs.

Oscillation and lung expansion therapy devices (e.g., Volara System, MetaNeb 4 System, and BiWaze Clear System) integrate multiple therapeutic modalities. These include continuous positive expiratory pressure (CPEP), continuous high-frequency oscillation (CHFO), and nebulized aerosol medication delivery. Collectively referred to as oscillation and lung expansion (OLE) therapy, these devices aim to facilitate airway clearance, promote lung expansion, prevent and treat atelectasis, and support the delivery of aerosolized medications and supplemental oxygen.

Mechanical Insufflation-Exsufflation Devices

Mechanical insufflation-exsufflation (MI-E), also known as cough assist devices or mechanical cough machines, is a noninvasive airway clearance technique that alternates positive pressure (insufflation) with rapid negative pressure (exsufflation) to mimic a natural cough. This approach enhances secretion mobilization, reduces the risk of respiratory complications, and may aid in ventilator weaning for select patient populations. MI-E is primarily indicated for individuals with impaired cough

due to neuromuscular disorders (e.g., amyotrophic lateral sclerosis [ALS], muscular dystrophy, and spinal muscular atrophy) or spinal cord injuries, where respiratory muscle weakness compromises effective secretion clearance.

Intrapulmonary Percussive Ventilation (IPV)

Intrapulmonary Percussive Ventilation (IPV) is a therapeutic modality designed to improve airway clearance and pulmonary function in individuals with respiratory conditions such as cystic fibrosis, chronic obstructive pulmonary disease (COPD), and bronchiectasis. The technique involves the delivery of rapid, small bursts of air at adjustable pressures and frequencies through a handheld device. These percussive bursts create internal airway vibrations that help mobilize mucus and secretions, facilitating their removal via coughing or suctioning.

IPV settings (e.g., frequency, pressure, and duration) can be customized to meet the specific clinical needs of each patient. The therapy may be administered invasively via an endotracheal or tracheostomy tube or noninvasively using a mask or mouthpiece. While IPV is utilized across various clinical specialties, current large-scale research does not provide conclusive evidence either supporting or refuting its efficacy in the treatment of diverse respiratory disorders.

Oscillation and Lung Expansion (OLE) Therapy

Oscillation and Lung Expansion (OLE) therapy is a non-invasive respiratory treatment that combines continuous positive expiratory pressure (CPEP), continuous high-frequency oscillation (CHFO), and aerosolized medication delivery (e.g., Volara System). This integrated approach supports airway clearance and lung expansion by mobilizing retained secretions and helping prevent or treat pulmonary atelectasis. OLE therapy may be indicated for patients with conditions that impair effective airway clearance or increase the risk of atelectasis, including neuromuscular disorders, chronic respiratory diseases, and post-operative pulmonary complications.

SUPPORTIVE LITERATURE

Lee et al (2015) published a Cochrane review on airway clearance techniques for treating bronchiectasis. Of the seven randomized controlled trials (RCTs) included, six were crossover trials. Five trials used a positive expiratory pressure (PEP) device, one used high frequency chest wall oscillation, and one used postural drainage. Reviewers did not pool study findings due to heterogeneity among studies. Primary outcomes of interest were pulmonary exacerbations, hospitalizations for bronchiectasis, and QOL.

Reychler et al (2018) conducted a systematic review to assess the physiological and clinical effectiveness of intrapulmonary percussive ventilation (IPV) as an airway clearance technique in individuals with COPD. The review included 12 studies (n=278), of which seven were randomized controlled trials (RCTs). The studies examined IPV use in patients with COPD (n=6 studies), CF (n=4 studies), and bronchiectasis (n=2 studies). Eligible studies assessed either immediate or long-term outcomes related to physiological parameters (e.g., blood gases, lung function, sputum production) or clinical effects. Exclusion criteria included studies involving children under five years of age, restrictive lung diseases, or IPV used outside the context of airway clearance. IPV was compared against six different airway clearance techniques, comparators varied and were not consistently

standardized or widely recognized. Few adverse events were reported. However, limitations such as small sample sizes, variability in treatment protocols, and heterogeneity in outcome measures led the authors to conclude that the evidence supporting IPV was inconsistent and insufficient to recommend its routine use. They emphasized the need for further research, particularly in CF populations, to assess IPV's role in airway clearance and its potential to improve early obstructive lung disease and ventilation heterogeneity.

Nicolini et al (2018) conducted a prospective, 4-week parallel randomized trial to evaluate the safety and effectiveness of high-frequency chest wall oscillation (HFCWO) versus IPV in patients with severe COPD. Sixty patients were randomized into three groups: IPV group (treated with pharmacological therapy [PT] and IPV), PT group (treated with PT and HFCWO), and control group (treated with PT alone). Treatments were administered over two weeks, with evaluations conducted one week before and one week after the intervention. The study assessed changes in pulmonary function, arterial blood gases, dyspnea scores, sputum production, and patient satisfaction. Results showed that while pulmonary function parameters (FEV_1 and FVC) did not significantly change in any group, both IPV and HFCWO improved oxygenation (PaO_2), with IPV showing a greater effect. IPV also resulted in significantly higher sputum production and greater reduction in dyspnea scores compared to HFCWO ($p<0.001$). Patient satisfaction was higher in the IPV group, and no serious adverse events were reported in any group. Despite its promising findings, the study's limitations (e.g., small sample size, short intervention and follow-up duration, and single-center design) warrant caution. The authors concluded that both HFCWO and IPV are safe and effective adjuncts to pharmacological therapy in severe COPD, with IPV showing superior outcomes in several clinical measures. They recommended further research involving larger populations and extended follow-up to validate these results and explore long-term benefits.

In a Cochrane review, Morrison and Milroy (2020) conducted a systematic review of RCTs to evaluate oscillatory devices for treating patients with Cystic Fibrosis (CF), addressing a variety of oscillatory devices. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and QOL measures. Meta-analysis was limited due to the variety of devices, outcome measures, and lengths of follow-up used. Reviewers concluded that there was a lack of evidence supporting the superiority of oscillatory devices versus any other form of physical therapy, that one device was superior to another, and that there is a need for adequately powered RCTs with long-term follow-up.

In a 2021 Cochrane review, Morrow and colleagues assessed various cough augmentation techniques for people with chronic neuromuscular disorders. A total of 11 RCTs, involving 287 participants aged 3 to 73 years, were reviewed. The primary outcomes were intended to be the number and duration of unscheduled hospitalizations for acute respiratory exacerbations, but none of the included studies reported on these outcomes or on adverse events as primary or secondary measures. Some evidence suggested that cough augmentation techniques may improve peak cough flow compared to unassisted cough, but the certainty of this evidence was very low. There was insufficient evidence to determine the impact of these techniques on gaseous exchange, pulmonary function, quality of life, general function, or patient satisfaction. Limitations in study design and reporting restricted the ability to draw firm conclusions, and further research is needed to evaluate the safety and efficacy of these interventions.

Livnat et al (2021) conducted a randomized trial in 51 patients with bronchiectasis that compared autogenic drainage and oscillating PEP for daily airway clearance. Patients who had not previously performed airway clearance were included. After 4 weeks, the primary outcome (lung clearance index, calculated as the cumulative expired volume during the washout phase divided by the functional residual capacity) and forced expiratory volume in 1 second (FEV_1) did not differ between groups. Change in sputum quantity from randomization to study end did not differ between groups. The rate of exacerbations was not described, but some QOL measures improved throughout the study in both groups.

Daynes et al (2021) performed a systematic review and meta-analysis to evaluate the effectiveness of airway clearance devices in the management of COPD. A total of 18 RCTS, involving 855 participants with either stable COPD or acute exacerbations, were included. Eligible studies compared airway clearance devices, such as positive expiratory pressure (PEP), oscillating PEP, and HFCWO, to usual care, sham interventions, or breathing exercises. Primary outcomes assessed included sputum volume, exacerbation frequency, hospitalizations, health-related quality of life (HRQoL), and symptom burden. The meta-analysis found that airway clearance devices significantly improved sputum clearance. Exacerbation frequency was significantly reduced at six months ($p<0.01$). Improvements were also observed in symptom scores, including the COPD Assessment Test (CAT) and the Breathlessness, Cough, and Sputum Score (BCSS), $p<0.01$, respectively. However, no statistically significant improvements were found in HRQoL as measured by the St. George's Respiratory Questionnaire (SGRQ). The review noted moderate to substantial heterogeneity across studies and classified the overall quality of evidence as low to moderate. Limitations included variability in study design, small sample sizes, and inconsistent outcome reporting. The authors concluded that airway clearance devices may be beneficial in improving sputum clearance, reducing exacerbations, and alleviating symptoms in stable COPD, but emphasized the need for higher-quality trials to confirm these findings and guide clinical recommendations.

Daynes et al (2022) conducted a double-blind, randomized, sham-controlled trial conducted to evaluate the effectiveness of a combined inspiratory muscle training (IMT) and high-frequency airway oscillating (HFAO) device in managing dyspnea in patients with COPD. A total of 104 symptomatic COPD patients were randomized to receive either the active HFAO device (Aerosure) or a sham device for an 8-week period, with usage prescribed three times daily. The primary outcome was the dyspnea domain of the Chronic Respiratory Questionnaire (CRQ-D), and secondary outcomes included respiratory muscle strength, sputum clearance, and subgroup analyses of patients with respiratory muscle weakness, excessive sputum, and frequent exacerbations. Of the enrolled participants, 96 completed the study. Results indicated no statistically significant difference between the HFAO and sham groups in CRQ-D scores ($p=0.24$), although showed clinically meaningful improvements over time. Notably, maximal inspiratory pressure improved significantly in the HFAO group compared to the sham group ($p=0.05$), with similar trends observed in subgroup analyses. Study limitations included the short duration of intervention, potential placebo effects due to the sham device, and the absence of long-term follow-up. The authors concluded that while the HFAO device did not demonstrate clinical superiority over the sham device for the primary outcome, it did yield significant improvements in certain secondary measures. They recommended further research

to explore long-term outcomes and refine patient selection criteria for device-based interventions in COPD management.

In a Cochrane review, Main and Rand (2023) conducted a review that included 21 randomized or quasi-RCTs involving 778 participants with CF, ranging from newborns to 45 years old. The studies compared conventional CPT (CCPT) with various alternative airway clearance techniques (ACTs), such as PEP devices, active cycle of breathing techniques (ACBT), autogenic drainage (AD), oscillating PEP devices, high-frequency chest compression, and exercise. Across short-, medium-, and long-term durations, the review found no consistent evidence that alternative ACTs were superior to CCPT in improving lung function, reducing respiratory exacerbations, or enhancing quality of life, adherence, or exercise capacity. Most studies suggested equivalence between CCPT and alternative ACTs, though the certainty of evidence was very low. Side effects were generally mild and infrequent. Participant preference often favored self-administered techniques, but variability in study design and outcome measures limited the ability to draw firm conclusions.

Veldhoen et al (2023) conducted a systematic review and meta-analysis to evaluate the effects of daily use of mechanical insufflation-exsufflation (MI-E) in patients with neuromuscular diseases (NMDs) who were clinically stable. A total of 25 studies (only 3 RTC) involving 608 subjects were included. The review excluded studies focused on acute respiratory failure or infections and those comparing different MI-E devices or settings. Outcomes assessed included respiratory infection prevalence and severity, lung function, respiratory characteristics, and patient satisfaction. The meta-analysis showed an overall beneficial effect of MI-E on cough peak flow (CPF) compared to unassisted CPF ($p<0.001$). Patient satisfaction was generally high, though subject to potential bias. However, the review concluded that limited evidence exists to support the benefits of daily MI-E use in stable NMD patients, with insufficient data to determine long-term effects.

Herrero-Cortina et al (2023) published the European Respiratory Society's official statement on ACTs for adults with bronchiectasis. A multidisciplinary task force of 14 clinical experts and two patient representatives from 10 countries reached consensus on six key questions. To evaluate the effectiveness of various ACTs (e.g., ACBT, autogenic drainage, percussions, PEP devices, positive expiratory pressure devices with oscillation [O-PEP], HFCWO, and IPV), the panel reviewed of 30 RCT (n=811 adults). Most studies were short-term, ranging from 1 day to 4 weeks, with only two extending to 3 and 12 months. Despite limited long-term data, findings suggest that ACTs can reduce cough severity, improve health-related quality of life (HRQoL), and lower the risk of exacerbations. No single technique demonstrated clear superiority over others, but the overall evidence supports the clinical use of ACTs in bronchiectasis management. The authors concluded that while the current evidence base remains limited, the available data show meaningful benefits and reinforce existing recommendations for incorporating ACTs into routine care. They emphasized the need for large-scale, prospective RCTs to assess the long-term impact of ACTs.

Hassan et al (2024) conducted the first scoping review of its kind to evaluate the clinical application of intrapulmonary percussive ventilation (IPV) across intensive care units (ICUs), acute inpatient (non-ICU), and outpatient settings. Although IPV has been used for several decades to manage a range of pulmonary conditions, evidence-based guidelines for its use remain lacking. The review included 25 studies involving 905 stable or acutely ill adults aged 16 years and older. These studies

utilized IPV, percussive ventilation, or high-frequency oscillation for therapeutic purposes. The findings revealed significant variability in IPV application and dosing protocols, though common clinical indications included management of excessive airway secretions, pulmonary atelectasis, and impaired gas exchange. Limitations of the review included heterogeneity in study designs, patient populations, and outcome measures, which precluded meta-analysis. Despite its widespread use, the authors emphasized the need for further research to establish standardized treatment protocols and strengthen the evidence base regarding IPV's clinical efficacy and safety.

Dierckx et al (2025) acknowledged the established efficacy of intrapulmonary percussive ventilation (IPV) in acute care settings, particularly for patients hospitalized due to COPD exacerbations. However, they noted that the routine use of IPV as an airway clearance technique (ACT) in stable COPD patients remains insufficiently supported by scientific evidence. In this prospective study, the authors investigated the effects of IPV in nonhospitalized patients with stable, severe to very severe COPD. Ten patients received IPV therapy three times weekly for four weeks, in addition to their standard treatment regimen. Clinical assessments (e.g., spirometry, body plethysmography, diffusion capacity, CT imaging, the Clinical COPD Questionnaire [CCQ], and six-minute walk tests [6MWD]) were conducted before and after the intervention. Nine patients completed the study. Results include: 6MWD increased from 329 m to 379 m (p=0.008), patient-reported outcomes trend toward improvement, mucus plug volume and count declined in patients with high baseline values, a decrease in lobe volume at the lobar level, measured at the TLC (p=0.003), and an increase in lobe volume at the lobar level (p=0.003). Additionally, the proportion of pulmonary blood in small pulmonary vessels (BV5%) decreased (p=0.044) at the lobar level, and distal deposition of triple therapy and short-acting beta2 mimetica (SABA) medication increased by 11% and 9%, respectively. The authors concluded that four weeks of IPV therapy may positively impact exercise capacity and patient-reported outcomes in stable COPD patients. These benefits were attributed to reduced hyperinflation, improved small airway recruitment, enhanced mucus clearance, better gas exchange, and increased distal deposition of inhaled medications. Despite promising results, the authors emphasized the need for larger, controlled studies to validate these findings and further explore IPV's role in stable COPD management.

Oscillation and Lung Expansion Therapy

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

PROFESSIONAL GUIDELINE(S)

American College of Chest Physicians (ACCP)

In 2018, the ACCP, also known as CHEST, published expert panel consensus-based suggestions for the management of cough in adults and children with non-cystic fibrosis (non-CF) and CF bronchiectasis (Hill 2018). The panel acknowledged that, although there is insufficient evidence to determine whether any specific ACT is consistently more effective than others for improving clinically important outcomes in CF bronchiectasis, this lack of high-quality evidence should not discourage the use of ACTs. Airway clearance remains a standard component of CF management. The ungraded consensus is for individualized ACTs for children and adults with productive cough due to

bronchiectasis, regardless of the underlying cause.

In 2023, the AACP clinical practice guideline and expert panel report on respiratory management of patients with neuromuscular weakness generated 15 graded recommendations, one good practice statement, and one consensus-based statement, including the following non-inclusive list: (Khan 2023)

- For patients with NMD and chronic respiratory failure, we recommend using non-invasive ventilation (NIV) for treatment (strong recommendation, very low certainty of evidence).
- For patients with NMD and reduced cough effectiveness, we suggest manually assisted cough techniques independently or added to other modalities such as lung volume recruitment (LVR) (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).
- For patients with NMD and difficulties with secretion clearance, we suggest using high-frequency chest wall oscillation (HFCWO) for secretion mobilization. In addition, we suggest that HFCWO be combined with airway clearance therapies such as cough assistance or LVR (conditional recommendation, very low certainty of evidence).

American Academy of Neurology (AAN)

In 2009 (reaffirmed in 2023) the AAN practice parameter update for the care of the patient with amyotrophic lateral sclerosis (ALS) recommends that MI-E may be considered to clear secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection (Level C). The AAN found that HFCWO is unproven for adjunctive airway secretion management and there is insufficient data to support or refute HFCWO for clearing airway secretions in patients with ALS (Level U).

Cystic Fibrosis Foundation

In 2009, clinical care guidelines recommended airway clearance therapy (ACT) for all individuals with cystic fibrosis (Flume 2009). The ACT methods 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. Based on available evidence, the Cystic Fibrosis Foundation found that no single ACT was superior to the others. These therapies support sputum clearance, enhance cough effectiveness, help maintain lung function, and improve quality of life.

The 2016 clinical practice guidelines for preschoolers with CF came to consensus recommendations that included daily airway clearance, with increased frequency and/or duration during pulmonary exacerbations (Lahiri 2016).

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates airway clearance devices as medical devices. All airway clearance devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 25]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2025 Oct 25]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

HCPCS Codes

Code	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
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
E0481	Intrapulmonary percussive ventilation system and related accessories
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

High Frequency Chest Wall Oscillation Devices (LCD L33785) [accessed 2025 Oct 25]

Intrapulmonary Percussive Ventilation System (LCD L33786) [accessed 2025 Oct 25]

Mechanical In-exsufflation Devices (LCD L33795) [accessed 2025 Oct 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 03/21/02, 05/21/03, 04/15/04, 04/21/05, 02/16/05, 01/18/07, 01/17/08, 12/18/08, 12/17/09, 02/17/11, 11/17/11, 12/20/12, 12/19/13, 12/18/14, 12/17/15, 11/17/16, 12/21/17, 12/20/18, 12/19/19, 12/17/20, 12/16/21, 12/22/22, 11/16/23, 11/21/24, 11/20/25

Date	Summary of Changes
11/20/25	• Annual review; revised conservative treatment requirements from "and" to an "or" statement for a positive policy intent change. Removed criteria that is not

	managed, separated criteria for high frequency chest wall compression and intrapulmonary percussive ventilation devices into two distinct policy statements, added CPT code E0469, and made clarifying edits- policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date