Airway Clearance Devices in the Home Setting

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DESCRIPTION

Note: This medical policy only applies to airway clearance devices in the home setting.

Cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome, neuromuscular diseases with progressive respiratory muscle weakness, and some acute respiratory tract infections are conditions that can lead to abnormal airway clearance or increase sputum production.

Chest physiotherapy also known as chest physical therapy (CPT) is a treatment that attempts to compensate for abnormal airway clearance by removing mucopurulent secretions. The standard of care continues to be manual clapping, vibration, compression, postural drainage, and assisted coughing. A physical therapist or another trained adult in the home administers CPT, which may be required for a period of 20-30 minutes from 1-3 times per day, depending on the severity of disease and the presence of intercurrent infection.

CPT to remove accumulated secretions requires a caregiver's assistance and may be burdensome and cause children/adolescents and adults to be less compliant with a treatment regimen as they wish to lead more independent lifestyles or a skilled caregiver is not available to assist in therapy.

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 cystic fibrosis patients.

Bronchiectasis, a chronic illness characterized by permanent and abnormal dilation of bronchi, presents with symptoms of recurrent cough, purulent sputum (often in excessive amounts), dyspnea, and hemoptysis. Bronchiectasis is common in patients with cystic fibrosis and chronic obstructive pulmonary disease. Non-cystic fibrosis bronchiectasis is most often suspected in patients with a chronic cough and sputum production with respiratory infections that are recurrent, severe, or persistent. Diagnosis of bronchiectasis requires confirmation by CT scan.

Use of airway clearance devices in those with neuromuscular disease has been the subject of multiple studies focusing on coughing/expectorant ability and effect on pulmonary exacerbation. Neuromuscular weakness can lead to compromise of the respiratory system, inadequate muscle tone of the upper airway, and the inability to adequately clear secretions. Consequently, this can lead to hypoventilation, obstruction of the airway, aspiration, retention of secretions, and infection. These complications often occur simultaneously and can ultimately lead to respiratory failure.

High-Frequency Oscillatory Chest Compression Devices (HFCWO)

High frequency chest compression (HFCC), also known as high frequency chest wall oscillation. (HFCWO) devices are used as alternatives to conventional chest physiotherapy (CPT) in patients with impaired ability to clear secretions from the respiratory tract. HFCWO consists of non-stretchable, inflatable vest connected by hoses to a small air-pulse generator. Small volumes of air are injected into and withdrawn from the vest at a rapid rate, creating vibrations that are transmitted across and through the chest wall of the person wearing the device. These transmitted vibrations cause a change in the airflow pattern within the airways. This changed or disrupted airway pattern may assist in loosening retained secretions, thus moving mucous towards the larger airways where it can be cleared by coughing. HFCWO are passive oscillatory devices designed to provide airway clearance without the active participation of the patient. There are two types of HFCWO devices to choose from: the traditional air bladder or compressor-based and mechanical motor-based vests.

- Air bladder HFCWO is an older technology and more restrictive for the patient as far as ease of use and portability.

- Mechanical oscillation vest therapy allows patients to get the same type of oscillation therapy but with full mobility during use and more flexibility, to promote compliance to the therapy.

Intrapulmonary Percussive Ventilator (IPV)
Intrapulmonary Percussive Ventilation (IPV) devices are a type of pneumatic, oscillating pressure breathing device that is designed to loosen mucus by internally percussing the airways using high frequency, high flow, and low-pressure bursts of gas (mini bursts) delivered via a mouthpiece, mask, or endotracheal tube. The user actuates a thumb control to trigger 15 to 25 high frequency pulses of air during inspiration and releases the control to allow for passive exhalation. Airway pressures oscillate between 5 and 35 cm H_2O, and the walls of the airways vibrate synchronously with these oscillations. A Venturi type system, powered by compressed gas, generates the oscillations at a rate of 100 to 300 cycles per minute. in contrast to PEP and flutter, IPV allows continuous monitored positive pressure application and percussion throughout the respiratory cycle. The patient controls adjustable variables such as inspiratory time, peak pressure and delivery rates. Additionally, some devices are designed to deliver aerosolized medications, such as bronchodilators and mucolytics, as well as other pulmonary therapies such as bi-level positive airway pressure (BiPAP) and continuous positive expiratory pressure (CPEP). The clinical utility of the device is purportedly to loosen retained secretions by means of these airway oscillations, and it has been investigated in the treatment of individuals suffering from secretion retention (particularly that associated with CF), as well as atelectasis.

Mechanical Insufflation – Exsufflation Device
A mechanical insufflation-exsufflation device is an example of a cough stimulation apparatus. It helps facilitate secretion clearance by applying positive pressure to the airway and then rapidly shifts to negative pressure. The quick pressure changes trigger a high expiratory flow rate mimicking a cough.

A report by the American College of Chest Physicians 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 seconds. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold."

Mechanical Percussor
A mechanical percussor is used instead of clapping the chest with cupped hands. The device is applied to the chest wall which vibrates or applies kinetic energy to the thorax/lung segments being drained at regular intervals. It may be used by a caregiver or independently by the patient.

Vibratory/Oscillatory Positive Expiratory Pressure (PEP) Devices
An oscillating positive expiratory pressure (PEP) device combines positive expiratory pressure with airway oscillation. The device is pipe-shaped with a mouthpiece at one end and a steel ball in a hard plastic housing at the other end. As the patient exhales, the steel ball rolls and vibrates producing oscillations in pressure which are transmitted throughout the tracheobronchial tree. The angle at which the device is held determines the amount of vibration. The oscillations dislodge mucous from the airway walls and the increased pressure maintains the patency of the airway so that mucous does not become trapped as it moves up the airway. Some oscillating PEP equipment is considered to be a flutter device (e.g., Flutter®, Acapella®).

Clinical Context and Therapy Purpose
The purpose of airway clearance devices for therapy in patients who have a disease requiring airway clearance and provide a treatment option that is an alternative or an improvement to existing therapies.

The question addressed in this evidence review is: Does use of oscillatory devices improve health outcomes in patients with a disease requiring airway clearance?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with a disease requiring airway clearance device.

Interventions
The therapy being considered is the application of airway clearance devices. Airway clearance devices are intended to be used primarily in the home setting by patients themselves.

Comparators
The following therapy is currently being used: standard chest physical therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions, quality of life (QOL), hospitalizations, and medication use. Changes in outcomes over a minimum 3-month period should be considered meaningful.

Literature

Bronchiectasis
(2016) Herrero-Cortina et al completed a randomized crossover trial. It consisted of 31 outpatients with bronchiectasis and chronic sputum expectoration. The interventions in cluded autogenic drainage (AD), slow expiration with glottis opened in lateral posture (ELTGOL), and temporary positive expiratory pressure (TPEP) The authors noted a

median (interquartile range) daily expectoration at baseline was 21.1 (15.3 to 35.6) g. During physiotherapy sessions, AD and ELTGOL expectorated more sputum than TPEP [AD vs TPEP 3.1g (95% CI 1.5 to 4.8); ELTGOL vs TPEP 3.6g (95% CI 2.8 to 7.1)], while overall expectoration in the 24-hour period after each session was similar for all techniques (P=0.8). Sputum clearance at 24hours post-intervention was lower than baseline assessment for all techniques [AD vs baseline -10.0g (95% CI -15.0 to -6.8); ELTGOL vs baseline -9.2g (95% CI -14.2 to -7.9); TPEP vs baseline -6.0g (95% CI -12.0 to -6.1)]. The LCQ score increased with all techniques (AD 0.5, 95% CI 0.1 to 0.5; ELTGOL 0.9, 95% CI 0.5 to 2.1; TPEP 0.4, 95% CI 0.1 to 1.2), being similar for all ACTs (P=0.6). No changes in lung function were observed.

The authors concluded slow expiratory ACTs enhance mucus clearance during treatment sessions and reduce expectoration for the rest of the day in patients with bronchiectasis. They also noted potential limitations of this study include the sample size calculation being based on patients with cystic fibrosis (due to similarities in clinical manifestations) because of the lack of data related to the primary endpoint in bronchiectasis. Participants and the physiotherapist were not blinded due to the characteristics of the interventions; however, the physiotherapist had lengthy experience with ACTs, reducing performance bias, while subjective outcomes were reported by patients, limiting detection bias. Although wet sputum quantity is considered to be a controversial outcome to assess mucus clearance (saliva contamination or secretion swallowing), no study to date has evaluated the psychometric properties, and the crossover design of this study may reduce this potential bias. Moreover, the amount of sputum collected over the 24-hour period after each session depends on patient compliance. Nevertheless, 24-hour sputum containers were weighed immediately after the assessment period, and no differences were observed between the 3 days of the same treatment. Furthermore, the efficacy of slow expiratory ACTs in patients with limited expectoration (<15 g) remains unknown.

(2015) Lee et al completed a randomized controlled parallel and cross-over trials that compared an ACT versus no treatment, sham ACT or directed coughing in participants with bronchiectasis. Seven studies involving 105 participants met the inclusion criteria of this review, six of which were cross-over in design. Six studies included adults with stable bronchiectasis; the other study examined clinically stable children with bronchiectasis. Three studies provided single treatment sessions, two lasted 15 to 21 days and two were longer-term studies. Interventions varied; some control groups received a sham intervention and others were inactive. The methodological quality of these studies was variable, with most studies failing to use concealed allocation for group assignment and with absence of blinding of participants and personnel for outcome measure assessment. Heterogeneity between studies precluded inclusion of these data in the meta-analysis; the review is therefore narrative. One study including 20 adults that compared an airway oscillatory device versus no treatment found no significant difference in the number of exacerbations at 12 weeks (low-quality evidence). Data were not available for assessment of the impact of ACTs on time to exacerbation, duration or incidence of hospitalization or total number of hospitalized days. The same study reported clinically significant improvements in HRQoL on both disease-specific and cough-related

measures. The median difference in the change in total St George's Respiratory Questionnaire (SGRQ) score over three months in this study was 7.5 units (P value = 0.005 (Wilcoxon)). Treatment consisting of high-frequency chest wall oscillation (HFCWO) or a mix of ACTs prescribed for 15 days significantly improved HRQoL when compared with no treatment (low-quality evidence). Two studies reported mean increases in sputum expectoration with airway oscillatory devices in the short term of 8.4 mL (95% confidence interval (CI) 3.4 to 13.4 mL) and in the long term of 3 mL (P value = 0.02). HFCWO improved forced expiratory volume in one second (FEV1) by 156 mL and forced vital capacity (FVC) by 229.1 mL when applied for 15 days, but other types of ACTs showed no effect on dynamic lung volumes. Two studies reported a reduction in pulmonary hyperinflation among adults with non-positive expiratory pressure (PEP) ACTs (difference in functional residual capacity (FRC) of 19%, P value < 0.05; difference in total lung capacity (TLC) of 703 mL, P value = 0.02) and with airway oscillatory devices (difference in FRC of 30%, P value < 0.05) compared with no ACTs. Low-quality evidence suggests that ACTs (HFCWO, airway oscillatory devices or a mix of ACTs) reduce symptoms of breathlessness and cough and improve ease of sputum expectoration compared with no treatment (P value < 0.05). ACTs had no effect on gas exchange, and no studies reported effects of antibiotic usage. Among studies exploring airway oscillating devices, investigators reported no adverse events.

The authors' conclusions note ACTs appear to be safe for individuals (adults and children) with stable bronchiectasis and may account for improvements in sputum expectoration, selected measures of lung function, symptoms and HRQoL. The role of these techniques in acute exacerbation of bronchiectasis is unknown. In view of the chronic nature of bronchiectasis, additional data are needed to establish the short-term and long-term clinical value of ACTs for patient-important outcomes and for long-term clinical parameters that impact disease progression in individuals with stable bronchiectasis, allowing further guidance on prescription of specific ACTs for people with bronchiectasis.

Chronic Obstructive Pulmonary Disease (COPD)

(2018) Nicolini et al reported the results of a single-blind randomized clinical trial involving 60 subjects with severe chronic obstructive pulmonary disease (COPD). Subjects were assigned to one of three groups: 1) IPV with P/PD, 2) high-frequency chest wall oscillation (HFCWO) with P/PD, and 3) P/PD alone. Subjects were treated for a period of 2 weeks and evaluated 1 week after completion. Compared to the control group, both IPV and HFCWO significantly improved scores on the Breathlessness, Cough and Sputum scale (BCSS), modified Medical Research Council (mMRC) scale and COPD Assessment Test (CAT) (no p-values provided). When compared to HFCWO, IPV resulted in significantly better scores on the BCSS and CAT scales ($p<0.001$ and $p<0.02$, respectively). Additionally, IPV improved total lung capacity (TLC, $p<0.03$) and TLC% ($p<0.04$), residual volume (RV) and RV% ($p<0.04$ for both), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal expiratory pressure (MEP; $p<0.01$ for all). No COPD exacerbations were reported during the study period. While the results of the study are promising, data from larger trials of longer

duration are warranted to better understand the durability of the findings, including evaluation of net health outcomes. Use of a sham control group is important to assess the impact of subject measures such as dyspnea.

(2016) Svenningsen et al completed a randomized crossover trial for daily oPEP use. Fourteen COPD patients, self-identified as sputum-producers and 13 COPD-non-sputum-producers completed the study. Post-oPEP, the PEQ-ease-bringing-up-sputum was improved for sputum-producers ($p = 0.005$) and non-sputum-producers ($p = 0.04$), the magnitude of which was greater for sputum-producers ($p = 0.03$). There were significant post-oPEP improvements for sputum-producers only for FVC ($p = 0.01$), 6MWD ($p = 0.04$), SGRQ total score ($p = 0.01$) as well as PEQ-patient-global-assessment ($p = 0.02$). Clinically relevant post-oPEP improvements for PEQ-ease-bringing-up-sputum/PEQ-patient-global-assessment/SGRQ/VDP were observed in 8/7/9/6 of 14 sputum-producers and 2/0/3/3 of 13 non-sputum-producers. The post-oPEP change in 3He MRI VDP was related to the change in PEQ-ease-bringing-up-sputum ($r = 0.65$, $p = 0.0004$) and FEV1 ($r = –0.50$, $p = 0.009$). The authors concluded COPD patients with chronic sputum production, PEQ and SGRQ scores, FVC and 6MWD improved post-oPEP. FEV1 and PEQ-ease-bringing-up-sputum improvements were related to improved ventilation providing mechanistic evidence to support oPEP use in COPD.

(2013) Goktalay et al completed a randomized controlled trial from April 2009 to July 2011, a total of 99 patients were assessed for eligibility, 50 patients were enrolled and randomized into two groups. A total of 50 (100%) patients (25 in Group I and 25 in Group II) were followed up for five days. Application of high-frequency chest wall oscillation therapy resulted in no significant advantage in all outcomes ($p > 0.05$). Mean (SD) baseline BODE index value in Group I was 7.72 (1.76), in Group II was 7.72(1.89) ($p = 0.55$). On the fifth-day assessment, mean (SD) BODE index value in Group I was 7.24 (1.83), in group II was 6.44 (2.46) ($p = 0.18$). The authors concluded the application of high-frequency chest wall oscillation therapy offers no additional advantages on infective exacerbations in chronic obstructive pulmonary disease.

Cystic Fibrosis

(2020) Morrison and Milroy completed a meta-analysis review, identified 82 studies (330 references); 39 studies (total of 1114 participants) met the inclusion criteria. Studies varied in duration from up to one week to one year; 20 of the studies were cross-over in design. The studies also varied in type of intervention and the outcomes measured, data were not published in sufficient detail in most of these studies, so meta-analysis was limited. Few studies were considered to have a low risk of bias in any domain. It is not possible to blind participants and clinicians to physiotherapy interventions, but 13 studies did blind the outcome assessors. The quality of the evidence across all comparisons ranged from low to very low. Forced expiratory volume in one second was the most frequently measured outcome and while many of the studies reported an improvement in those people using a vibrating device compared to before the study, there were few differences when comparing the different devices to each other or to other airway clearance techniques. One study identified an increase in frequency of exacerbations

requiring antibiotics whilst using high frequency chest wall oscillation when compared to positive expiratory pressure (low-quality evidence). There were some small but significant changes in secondary outcome variables such as sputum volume or weight, but not wholly in favor of oscillating devices and due to the low- or very low-quality evidence, it is not clear whether these were due to the particular intervention. Participant satisfaction was reported in 13 studies but again with low- or very low-quality evidence and not consistently in favor of an oscillating device, as some participants preferred breathing techniques or techniques used prior to the study interventions. The results for the remaining outcome measures were not examined or reported in sufficient detail to provide any high-level evidence.

There was no clear evidence that oscillation was a more or less effective intervention overall than other forms of physiotherapy; furthermore, there was no evidence that one device is superior to another. The findings from one study showing an increase in frequency of exacerbations requiring antibiotics whilst using an oscillating device compared to positive expiratory pressure may have significant resource implications. More adequately powered long-term randomized controlled trials are necessary and outcomes measured should include frequency of exacerbations, individual preference, adherence to therapy and general satisfaction with treatment. Increased adherence to therapy may then lead to improvements in other parameters, such as exercise tolerance and respiratory function. Additional evidence is needed to evaluate whether oscillating devices combined with other forms of airway clearance is efficacious in people with cystic fibrosis. There may also be a requirement to consider the cost implication of devices over other forms of equally advantageous airway clearance techniques. Using the GRADE method to assess the quality of the evidence, authors judged this to be low or very low quality, which suggests that further research is very likely to have an impact on confidence in any estimate of effect generated by future interventions.

(2018) Radtke et al completed a prospective, randomized crossover study compared a single bout of continuous cycling exercise at moderate intensity (experiment A, control condition) vs a combination of interval cycling exercise plus Flutter® (experiment B). Sputum properties (viscoelasticity, yield stress, solids content, spinnability, and ease of sputum expectoration), pulmonary diffusing capacity for nitric oxide (DLNO) and carbon monoxide (DLCO) were assessed at rest, directly and 45 min post-exercise (recovery) at 2 consecutive visits. Primary outcome was change in sputum viscoelasticity (G', storage modulus; G", loss modulus) over a broad frequency range (0.1-100 rad.s- 1). Results included 15 adults with CF (FEV1range 24-94% predicted) completed all experiments. No consistent differences between experiments were observed for G' and G" and other sputum properties, except for ease of sputum expectoration during recovery favoring experiment A. DLNO, DLCO, alveolar volume (VA) and pulmonary capillary blood volume (Vcap) increased during experiment A, while DLCO and Vcap increased during experiment B (all $P < 0.05$). We found no differences in absolute changes in pulmonary diffusing capacity and its components between experiments, except a higher VA immediately post-exercise favoring experiment A ($P = 0.032$). The authors noted the additional use of the Flutter® to moderate intensity interval cycling exercise has no

measurable effect on the viscoelastic properties of sputum compared to moderate intensity continuous cycling alone. Elevations in diffusing capacity represent an acute exercise-induced effect not sustained post-exercise.

(2016) Morgan et al 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. The 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.

(2013) McIlwaine completed a randomized controlled study was performed in 12 CF centers in Canada. After a 2-month washout period, subjects were randomized to perform either HFCWO or PEP mask therapy for 1 year. Results included 107 subjects were enrolled in the study; 51 were randomized to PEP and 56 to HFCWO. There were 19 dropouts 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 vs 2.0 for HFCWO) and time to first PE (220 days for PEP vs 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 two groups. PEP mask therapy required a shorter treatment time. The authors noted the results of the

study favor PEP and do not support the use of HFCWO as the primary form of AC in patients with CF.

(2006) Cantin et al 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.

Miscellaneous

(2006) Reychler et al stated 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.

Respiratory Conditions Related to Neuromuscular Disorders/ Neuromuscular Disorders

(2014) Winfield et al completed a systemic review and noted fifteen studies were included in the review. Studies included children with a range of severe neurological impairments in differing settings, for example, home and critical care. Several different treatment modalities were assessed, and a wide range of outcome measures were used. Most studies used a non-randomized design and included small sample groups. Only four randomized controlled trials were identified. Non-randomized design, lack of information about how participants were selected and who completed outcome measures and incomplete reporting led to high or unclear risk of bias in many studies. Results from

low-quality studies suggest that use of non-invasive ventilation, mechanically assisted coughing, high-frequency chest wall oscillation (HFCWO), positive expiratory pressure and supportive seating may confer potential benefits. No serious adverse effects were reported for ventilatory support or airway clearance interventions other than one incident in a clinically unstable child following mechanically assisted coughing. Night-time positioning equipment and spinal bracing were shown to have a potentially negative effect for some participants. However, these findings must be considered as tentative and require testing in future randomized trials. The authors' concluded no high-quality evidence for any single intervention for the management of respiratory morbidity in children with severe global developmental delay. Our search yielded data on a wide range of interventions of interest. Significant differences in study design and in outcome measures precluded the possibility of meta-analysis. No conclusions on efficacy or safety of interventions for respiratory morbidity in children with severe global developmental delay can be made based upon the findings of this review. A coordinated approach to future research is vital to ensure that high-quality evidence becomes available to guide treatment for this vulnerable patient group.

(2010) Yuan et al 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.

(2008) Brückner 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 usually demands 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 cannot 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.

(2006) Lange et al did an *exploratory* randomized controlled trial, 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.

(2006) Chaisson et al 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. They did not find HFCWO to be of significant help to patients with ALS.

Summary of Evidence
Based on the analysis of the published peer reviewed literature evaluating airway clearance devices; high frequency oscillatory chest compression devices (HFCWO), mechanical insufflation – exsufflation devices, mechanical percussors, and vibratory/oscillatory positive expiratory pressure (PEP) devices for conditions such as cystic fibrosis, chronic diffuse bronchiectasis and who have a significant impairment of chest wall and/or diaphragmatic movement.

It has been theorized the 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, the devices 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 specific conditions where manual chest physiotherapy is unavailable and/or not tolerated.

The devices have been promoted for use in conditions other than CF, including non-CF bronchiectasis. However, there are no adequate or limited published controlled clinical studies for conditions other than CF. Given the unique pathophysiology of CF resulting in the abnormal composition of CF secretions, evidence of the effectiveness airway devices in CF cannot be extrapolated to other pulmonary conditions. Airway clearance devices have been approved for a wide variety of pulmonary conditions based on 510(k) pre-market notifications; thus, the manufacturers were not required to submit the type of evidence of effectiveness that would be required to support a pre-market approval (PMA) application.

While more studies may be indicated preliminary results noted the devices to be safe and effective as well as adherence to prescribed regimen was higher with airway clearance devices. These findings suggest safety, tolerability, and better compliance with airway clearance devices. Improvement in airway clearance may also help prevent hospitalizations. Therfore the evidence is sufficient in supporting the use of airway clearance devices for conditions such as cystic fibrosis, chronic diffuse bronchiectasis and who have a significant impairment of chest wall and/or diaphragmatic movement. Intrapulmonary percussive ventilator (e.g., the Percussionaire and the TXP® Universal VENTILATOR Percussionator®, Volara). 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.

Combination high frequency chest oscillation and positive expiratory pressure systems (e.g., MetaNeb) system has not been studied in the home setting.

Simeox Airway Clearance Device is not currently FDA approved.

Based on the review of the current evidenced based peer reviewed literature the evidence is insufficient to determine the technology improves net health outcomes. Further randomized controlled trials, in the home setting, with long term outcomes need to be completed. Also, the Simeox Airway Clearance device has not been approved by the FDA.

Practice Guideline and Position Statements

American College of Chest Physicians (ACCP)
(2006) The ACCP indicates that devices designed to oscillate gas in the airway (e.g., Flutter, Intrapulmonary Percussive Ventilation, HFCWC), either directly or by compressing the chest wall, may be considered an alternative to chest PT in patients with CF (level of evidence, low; benefit, conflicting; grade of recommendation, inconclusive). (*Accessed December 2021*)

American Academy of Neurology (AAN)
(2009) The AAN completed an evidence-based review/practice parameter updated for the care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies which states the following:

- Mechanical insufflation/exsufflation (MIE) may be considered to clear secretions in patients with ALS who have reduced peak cough flow, particularly during an acute chest infection (Level C).
- There are insufficient data to support or refute HFCWO for clearing airway secretions in patients with ALS (Level U).

(*Accessed December 2021*)

American Association for Respiratory Care (AARC)
(2013) AARC clinical practice guidelines on non-pharmacologic airway clearance therapies in hospitalized patients state that, due to insufficient evidence, includes the following recommendation:

- Positive expiratory pressure (PEP), Intrapulmonary percussive ventilation (IPV) and High-frequency chest wall compression (HFCWC) cannot be recommended for adult or pediatric patients with neuromuscular disease (NMD), respiratory muscle weakness or impaired cough.

(*Accessed December 2021*)

American Thoracic Society (ATS)
(2004) The ATS made a consensus statement on the Respiratory Care of the Patient with Duchenne Muscular Dystrophy (DMD) and reported the following information:

- A recent case series including one patient with DMD reported the effectiveness of intrapulmonary percussive ventilation (IPV) in resolving persistent pulmonary consolidations refractory to conventional therapies.
- High frequency chest wall oscillation has been used in patients with neuromuscular weakness but there are no published data on which to base a recommendation.

- Any airway clearance device predicated upon normal cough is less likely to be effective in patients with DMD without concurrent use of assisted cough.

Recommendations included:

- Use assisted cough technologies in patients whose clinical history suggests difficulty in airway clearance, or whose peak cough flow is less than 270 L/minute and/or whose maximal expiratory pressures are less than 60 cm H2O.
- The committee strongly supports use of mechanical insufflation-exsufflation in patients with DMD and recommends further studies of this modality.

(*Accessed December 2021*)

Cystic Fibrosis Foundation

(2009) The Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence. The committee determined that, although there is a paucity of controlled trials that assess the long-term effects of ACTs, the evidence quality overall for their use in CF is fair and the benefit is moderate. The committee recommends airway clearance be performed on a regular basis in all patients. There are no ACTs demonstrated to be superior to others, so the prescription of ACTs should be individualized. (Level of evidence: fair; net benefit: moderate; grade of recommendation: B). (*Accessed December 2021*)

National Institute for Health and Clinical Excellence (NICE)

Cystic Fibrosis: Diagnosis and Management NICE Guideline:

- (2017, Updated 2021) In the guidance on the management of cystic fibrosis, do not offer high-frequency chest wall oscillation as an airway clearance technique for people with cystic fibrosis except in exceptional clinical circumstances. The specialist cystic fibrosis team will decide whether these circumstances apply, and their decision would then be subject to the NHS England policy on Individual Funding Requests. Be aware that the evidence shows high-frequency chest wall oscillation is not as effective as other airway clearance techniques. (*Accessed December 2021*)

Regulatory Status

Several airway clearance devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, *including but not limited to the following*:

High Frequency Oscillatory Chest Compression Devices (HFCWO)		
Device	**FDA 510(k) Approval Year**	**Description**
AffloVest (International Biophysics)	2013	It is designed to provide patients the freedom and mobility by a portable device which runs via battery pack, hose and generator. Patients can customize and enhance airway clearance therapy, help mobilize

		lung secretions, and promote treatment adherence for patients with Bronchiectasis, Cystic Fibrosis, COPD,MS, MD (muscular dystrophy), ALS, and other neuromuscular and respiratory diseases.
inCourage® System	2005	The InCourage system, a high-frequency chest wall oscillation (HFCWO) device features active venting, which is designed to enable deep breaths during therapy, enhance comfort and help encourage adherence for people with chronic respiratory conditions, like bronchiectasis, COPD, cystic fibrosis and various neuromuscular and neuromotor conditions.
MetaNeb® System (Hill-Rom)	2016	It delivers continuous high-frequency oscillation and positive expiratory pressure to facilitate pulmonary mucus clearance and provide lung expansion. The system is indicated for mobilizing lung secretions, lung expansion therapy, and treating and preventing pulmonary atelectasis. The device can be used in patients with chronic obstructive pulmonary disease, postoperative airway management, bronchiectasis, neuromuscular disorders, cystic fibrosis, asthma, emphysema, and chest wall trauma.
MedPulse® Respiratory Vest System (**different models available*)	2004	It produces oscillating pressurized air-pulses that are delivered to the Inflatable Vest by the Vest/Generator Hose. The air-pulses produced by the Generator cause the Vest to rapidly inflate and deflate against the external chest wall of a patient to promote airway clearance by creating HFCWO resulting in mobilization of bronchial secretions.
Monarch™ Airway Clearance System (Hill-Rom)	2017	It is a portable version of a high frequency chest wall oscillation device utilizing pulmonary oscillating discs (PODs) containing magnets, over the upper and lower lobes of the lungs.
Respin11 Bronchial Clearance System (Respinnovation)	2012	Developed for an effective therapy of airway obstruction conditions. The device is made up of a jacket connected to a vibration/pulsation generator. the pulsations are obtained by the pressure differences of a multistage blower. These pulsations are transmitted to the subject's chest through an air pressure piston system specially designed and inserted into the front and rear cavities of the vest provided. The compression then release cycle on the chest wall generates a differential air speed in the

		bronchial airway in the lungs. This produces a shearing effect which pulls the mucus off the bronchial airway walls and to then be moved through mucociliary action into the larger upper airways to then be eliminated naturally through coughing or if necessary, by external suction.
SmartVest (Electromed)	2013	Is designed to promote airway clearance and improve bronchial drainage when external chest manipulation is the physician's treatment of choice. The Air Pulse Generator produces small volumes of pressurized air pulses that are rapidly delivered to the Inflatable Vest via the Air Hose at a selected oscillatory frequency between 5-20 times per minute (Hz). The Inflatable Vest imparts the oscillatory air pulses as pressure forces to the patient's external chest wall. These pressurized air pulses promote transient increases in airflow within the lungs that loosens mucus sufficiently to facilitate expulsion by the patient when normal respiratory function is not capable.
Vest Airway Clearance System (Hill-Rom)	2003	It provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator creates pressure pulses that cause the vest to inflate and deflate against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions. This was originally approved in 1988 under ABI vest.

Intrapulmonary Percussive Ventilator		
Device	**FDA 510(k) Approval Year**	**Description**
Percussionaire *Multiple Products* *-IPV®-1C,* *-IPV®-2C* *-TRUE-IPV®*	_____	The device combines internal thoracic percussion through rapid mini bursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer. An aerosol machine that delivers bursts at various rates to the respiratory tract.

Mechanical Insufflation – Exsufflation Device		
Device	**FDA 510(k) Approval Year**	**Description**
CoughAssist	2020	It is designed to non-invasively inflate the lung with positive pressure and assist cough by shifting the air to negative pressure to help mobilize secretions out of the airway. A report by the American College of Chest Physicians 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 seconds. Using this technique of mechanical insufflation-exsufflation, peak cough expiratory flows can be increased by more than four-fold."

Mechanical Percussor		
Device	**FDA 510(k) Approval Year**	**Description**
Electro Flow® 6	2020	It is intended to provide Airway Clearance Therapy in the home and 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.

Miscellaneous Device(s)		
Device	**FDA 510(k) Approval Year**	**Description**
Pulsehaler™	2021	The Pulsehaler™ is indicated for use as a positive expiratory pressure (PEP) Device delivering vibrating air pressure pulses into the airway to assist in secretion clearance and airway opening. Air pulses are created by the interruption of the flow of air to and from the patient by a spinning disc.
Simeox Airway Clearance	*At this time, the device is*	Simeox technology is reported to mobilize and transport mucus from the distal tracts by

Technology (Physio Assist)	*not FDA approved for use in the United States.*	disseminating a vibratory pneumatic signal in the bronchial tree during exhalation.
Vibralung® Acoustical Percussor (Westmed)	2014	It is an *acoustical percussor* device that is battery-operated and portable. It applies vibratory sound waves directly to your airways through your mouth, at a multitude of frequencies. Reported to be s a gentler form of ACT than oscillatory PEP devices.
Volara™ System (Hill-Rom)	2020	This device is an oscillating and lung expansion (OLE) device, designed as a single device to provide therapies, continuous expiratory pressure (CPEP), continuous high flow oscillations (CHFO), and aerosolized medication.

Vibratory/Oscillatory Positive Expiratory Pressure (PEP) Devices		
Device	**FDA 510(k) Approval Year**	**Description**
Acapella® (DHD Healthcare)	1999	It is a small pipe-shaped, easily portable hand-held device, with a mouthpiece at one end. It contains a high-density stainless-steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs, resulting in loosening of mucus.
AerobiKA® oscillating PEP device (Trudell Medical)	2013	It is oscillating PEP (oPEP) device. It is a single patient use, handheld secretion clearance and lung expansion device that creates vibrating positive expiratory pressure when a patient exhales through the device. The device may be used simultaneously with aerosol drug delivery from a nebulizer.
FLUTTER® (Axcan Scandipharm)	1994	It is similar in concept as the Acapella but uses a counterweighted plug and magnet to create air flow oscillation.

PRIOR APPROVAL

Not applicable.

POLICY

Note: This medical policy only applies to airway clearance devices in the home setting.

High-Frequency Chest Wall Compression/High-Frequency Chest Wall Oscillator (E0483):

1. **Medically Necessary**

   The use of high-frequency oscillatory chest wall compression devices for airway clearance may be **medically necessary** in individuals with **one** of the following:

   - Chronic diffuse bronchiectasis and **one of the following**:
     - With a daily productive cough for at least six continuous months; **or**
     - With exacerbations requiring antibiotic therapy more than two times a year;

     And the following:
     - Confirmed by high resolution *or* spiral chest computed tomography scan; **or**
   - Cystic fibrosis; **or**
   - Immotile ciliary dysfunction/Primary ciliary dyskinesia; **or**
   - A neurodegenerative/neuromuscular disease with documented, associated respiratory muscle weakness or diaphragm paralysis

   And documentation of **one or more** of the following:

   - The caregiver is physically or mentally incapable of performing chest physiotherapy (CPT) as prescribed; **or**
   - No caregiver, parent, or partner resource available to perform standard chest physiotherapy (CPT) as prescribed; **or**
   - Standard chest physiotherapy (CPT) is not tolerated; **or**
   - Failure* of standard chest physiotherapy (CPT) to adequately mobilize retained secretions (e.g., prior history of pneumonia or worsening of pulmonary condition), when CPT has been performed as prescribed.

**Failure includes repeat respiratory infections or decreased breathing capacity when there is evidence that chest physiotherapy (CPT) has been consistently performed as prescribed.*

2. **Not Medically Necessary**

   The use of high-frequency chest wall compression devices are considered **not medically necessary** when the criteria above are not met including but not limited to the following indications:

   - Active hemorrhage with hemodynamic instability
   - Bronchospasm

- Burns, open wounds, and skin infections of the thorax
- Coagulopathy
- Complaint of significant chest wall pain
- Lung contusion
- Osteomyelitis of the ribs
- Osteoporosis
- Recent (90 days)
    - Epidural
    - Skin grafts or flaps on the thorax
    - Transvenous pacemaker or subcutaneous pacemaker
    - Spinal fusion
    - Spinal anesthesia
- Subcutaneous emphysema
- Suspected pulmonary tuberculosis
- Unstable head or neck injury

Mechanical Insufflation-Exsufflation Devices (E0482):

1. **Medically Necessary**

The use of mechanical insufflation-exsufflation devices for airway clearance may be considered **medically necessary** in individuals who have a significant impairment of chest wall and/or diaphragmatic movement when **one of the following** criteria are met:

- The individual can no longer be adequately treated with standard, manual chest physiotherapy (CPT); **or**
- Standard chest physiotherapy (CPT) is not tolerated.

2. **Not Medically Necessary**

The use of mechanical insufflation-exsufflation devices for airway clearance are considered **not medically necessary** when the medical necessity criteria above are not met.

Mechanical Percussors (E0480):

1. **Medically Necessary**

The use of mechanical percussors for airway clearance may be considered **medically necessar**y in individuals with **one of the following** indications:

- Chronic diffuse bronchiectasis and **one of the following**:
    - With a daily productive cough for at least six continuous months; **or**
    - With exacerbations requiring antibiotic therapy more than two times a year;

  And the following:
    - Confirmed by high resolution *or* spiral chest computed tomography scan; **or**
- Cystic fibrosis; **or**

- Immotile ciliary dysfunction/Primary ciliary dyskinesia; **or**
- A neurodegenerative/neuromuscular disease with documented, associated respiratory muscle weakness or diaphragm paralysis

And documentation of **one or more** of the following:

- The caregiver is physically or mentally incapable of performing chest physiotherapy (CPT) as prescribed; **or**
- No caregiver, parent, or partner resource available to perform standard chest physiotherapy (CPT) as prescribed; **or**
- Standard chest physiotherapy (CPT) is not tolerated; **or**
- Failure* of standard chest physiotherapy (CPT) to adequately mobilize retained secretions (e.g., prior history of pneumonia or worsening of pulmonary condition), when CPT has been performed as prescribed.

**Failure includes repeat respiratory infections or decreased breathing capacity when there is evidence that chest physiotherapy (CPT) has been consistently performed as prescribed.*

2. **Not Medically Necessary**
   The use of mechanical percussors for airway clearance are considered **not medically necessary** when the medical necessity criteria above are not met.

Oscillatory (Vibratory) Positive Expiratory Pressure Device (E0484/S8185)

1. **Medically Necessary**
   The use of an oscillatory (vibratory) positive expiratory pressure device for airway clearance is considered **medically necessary** in individuals diagnosed with **one of the following**:
   - Chronic bronchiectasis
   - Congenital bronchiectasis
   - Chronic bronchitis
   - Chronic obstructive pulmonary disease (COPD) with excessive secretion production
   - Cystic fibrosis

   And documentation of **all of the following:**
   - Have difficulty clearing secretions: **and**
   - Have recurrent disease exacerbations (e.g., Acute onset warranting additional treatment to the individual's underlying condition more than two times a year).

2. **Not Medically Necessary**
   The use of an oscillatory (vibratory) positive expiratory pressure device for airway clearance is considered **not medically necessary** when the medical necessity criteria above are not met.

Vibralung (E1399):

Note: The Vibralung is considered an upgraded percussor.

1. **Medically Necessary**

The use of the Vibralung airway clearance device may be considered **medically necessar**y in individuals with **one of the following** diagnoses:

- Chronic diffuse bronchiectasis and **one of the following**:
  - With a daily productive cough for at least six continuous months; **or**
  - With exacerbations requiring antibiotic therapy more than two times a year.

  And the following:
  - Confirmed by high resolution *or* spiral chest computed tomography scan; **or**
- Cystic fibrosis; **or**
- Immotile ciliary dysfunction/Primary Ccliary dyskinesia; **or**
- A neurodegenerative/neuromuscular disease with documented, associated respiratory muscle weakness or diaphragm paralysis

And documentation of **one or more** of the following:

- The caregiver is physically or mentally incapable of performing chest physiotherapy (CPT) as prescribed; **or**
- No caregiver, parent, or partner resource available to perform standard chest physiotherapy (CPT) as prescribed; **or**
- Standard chest physiotherapy (CPT) is not tolerated; **or**
- Failure* of standard chest physiotherapy (CPT) to adequately mobilize retained secretions (e.g., prior history of pneumonia or worsening of pulmonary condition), when CPT has been performed as prescribed.

And the following:

- Documentation must support a mechanical percussor cannot be used (i.e., burns, chest trauma, rib fracture).

**Failure includes repeat respiratory infections or decreased breathing capacity when there is evidence that chest physiotherapy (CPT) has been consistently performed as prescribed.*

2. **Not Medically Necessary**

The use of the Vibralung airway clearance device is considered **not medically necessary** when the medical necessity criteria above are not met.

Miscellaneous: Investigational:

The use of airway clearance devices for any other indication not listed above is considered **investigational** including but not limited to the following due to a lack of evidence demonstrating an impact on improved health outcomes:

- Combination high frequency chest oscillation and positive expiratory pressure systems (e.g., MetaNeb)
- Intrapulmonary Percussion Ventilation (E0481)
- Simeox Airway Clearance TechnoSlogy (E1399)
- Volara (E1399)

Replacement for Airway Clearance Devices (A7025, A7026):

1. Medically Necessary

The replacement of an existing airway clearance device is considered **medically necessary** when **one of the following** criteria are met:

- The individual meets the medical necessity criteria above for the specific airway clearance device and documentation confirms the airway clearance device is malfunctioning, no longer under warranty and cannot be repaired; **or**
- The individual meets the medical necessity criteria above for the specific airway clearance device and documentation from a health care provider recommending the replacement is needed due to growth or change of member's condition.

2. Not Medically Necessary

The replacement of an existing airway clearance device is considered **not medically necessary** including but not limited to the following:

- When the above medical necessity replacement criteria are not met.
- The replacement is solely for better technology or improved aesthetics.

Policy Guidelines

- **Definitions**
  - Bronchiectasis: A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or from a congenital condition.

  - Bronchitis: An inflammation of the upper airways associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last two or more years, a person has been coughing up some mucus every day for at least three months out of the year.

  - Chest physiotherapy (CPT) (also known as chest physical therapy): The use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This

technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is to improve mucociliary clearance and pulmonary function to reduce the risk of infection and lung damage.

- Cystic fibrosis (CF): An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- A7025 High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
- A7026 High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
- E0480 for Percussor device, electric or pneumatic, home model
- E0481 for intrapulmonary percussive ventilation system and related accessories
- E0482 for cough stimulating device, alternating positive and negative airway pressure (mechanical insufflation-exsufflation)
- E0483 for high frequency chest wall oscillation air-pulse generator system (includes hoses and vest), each
- E0484 for oscillatory positive pressure device, non-electric, any type, each
- E1399 Durable medical equipment, miscellaneous
- S8185 Flutter device

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POLICY HISTORY		
Date	**Reason**	**Action**
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Revised
September 2018	Annual Review	Policy Revised
September 2017	Annual Review	Policy Revised
May 2017	Annual Review	Policy Revised
May 2016	Annual Review	Policy Revised
June 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Revised
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232

Des Moines, IA 50306-9232

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