

UnitedHealthcare[®] Community Plan[EM1] Medical Policy

Instructions for Use

Airway Clearance Devices (for Louisiana Only)

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	Certain content mandated by Louisiana Department of Health
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Application

This Medical Policy only applies to the state of Louisiana. Portions of the coverage rationale contained in this policy represent Louisiana Medicaid coverage policy and are set forth below in accordance with state requirements.

Coverage Rationale

State Specific Criteria

High frequency chest wall oscillation devices (HCPCS code E0483) are covered for beneficiaries who meet the following criteria.

The beneficiary must have one of the following:

- A diagnosis of cystic fibrosis; or
- A diagnosis of bronchiectasis:
 - Characterized by daily productive cough for at least 6 continuous months or frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy; and
 - o Confirmed by high resolution, spiral, or standard CT scan
- or
- Neuromuscular disorder; or
- Well-documented failure of standard treatments to adequately mobilize retained secretions with all of the following:
 - Chest physical therapy and flutter device at least twice daily (when age appropriate);
 - A pattern of hospitalizations at least annually or more;
 - Significantly deteriorating clinical condition:
 - Be under the care of a pulmonologist; and
 - Copies of two pulmonary test results that indicate the beneficiary's condition improved with the use of the vest

Non State-Specific Criteria

Combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary.

Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not medically necessary.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
<u>*A7021</u>	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
*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
<u>*E0469</u>	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
*E0481	Intrapulmonary percussive ventilation system and related accessories
E0483	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

Diagnosis Code	Description
A80.0	Acute paralytic poliomyelitis, vaccine-associated
A80.1	Acute paralytic poliomyelitis, wild virus, imported
A80.2	Acute paralytic poliomyelitis, wild virus, indigenous
A80.30	Acute paralytic poliomyelitis, unspecified
A80.39	Other acute paralytic poliomyelitis
A80.4	Acute nonparalytic poliomyelitis
A80.9	Acute poliomyelitis, unspecified
B91	Sequelae of poliomyelitis
E74.02	Pompe disease
E74.4	Disorders of pyruvate metabolism and gluconeogenesis
E84.0	Cystic fibrosis with pulmonary manifestations
E84.9	Cystic fibrosis, unspecified
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy

Diagnosis Code	Description
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.25	Progressive spinal muscle atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Post-polio syndrome
G35	Multiple sclerosis
G71.00	Muscular dystrophy, unspecified
G71.11	Myotonic muscular dystrophy
G71.20	Congenital myopathy, unspecified
G71.21	Nemaline myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G71.3	Mitochondrial myopathy, not elsewhere classified
G71.8	Other primary disorders of muscles
G72.41	Inclusion body myositis [IBM]
G72.89	Other specified myopathies
G73.1	Lambert-Eaton syndrome in neoplastic disease
G73.3	Myasthenic syndromes in other diseases classified elsewhere
G73.7	Myopathy in diseases classified elsewhere
G80.0	Spastic quadriplegic cerebral palsy
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
J98.6	Disorders of diaphragm
M33.02	Juvenile dermatomyositis with myopathy
M33.12	Other dermatomyositis with myopathy
M33.22	Polymyositis with myopathy
M33.92	Dermatopolymyositis, unspecified with myopathy
M34.82	Systemic sclerosis with myopathy
M35.03	Sicca syndrome with myopathy
Q33.4	Congenital bronchiectasis
R53.2	Functional quadriplegia
Z99.11	Dependence on respirator [ventilator] status

Description of Services

In healthy individuals, clearance of secretions from the respiratory tract is accomplished primarily through ciliary action. Increased production of airway secretions is usually cleared by coughing. However, a number of conditions, including asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), mucociliary disorders, neuromuscular disease (NMD) and metabolic disorders can result in inadequate airway clearance, either because of increased volume of secretions increased viscosity of secretions, or difficulty in coughing. These secretions accumulate in the bronchial tree, occluding small passages and interfering with adequate gas exchange in the lungs. They also serve as a culture medium for pathogens, leading to a higher risk for chronic infection and deterioration of lung function. The blockage of mucus can result in Bronchiectasis, the abnormal stretching and enlarging of the respiratory passages. Bronchiectasis may complicate chronic bronchitis, one of the groups of respiratory illnesses referred to as COPD and it can occur as a complication of CF.

When coughing alone cannot adequately clear secretions, other therapies are used. Conventional chest physical therapy (CPT) has been shown to result in improved respiratory function and has traditionally been accomplished through the use of percussion and postural drainage. Postural drainage and percussion are usually taught to family members so that the therapy may be continued at home when needed in chronic disease. This highly labor-intensive activity requires the daily intervention of a trained caregiver which may lead to poor compliance with the recommended treatment plan.

To improve compliance and allow patients to independently manage their disease, HFCWC/high frequency chest wall oscillation (HFCWO) devices have been developed to improve mucociliary clearance and lung function. HFCWC is a mechanical form of CPT that consists of an inflatable vest connected by tubes to a small air-pulse generator. The air-pulse generator rapidly inflates and deflates the vest, compressing and releasing the chest wall up to 20 times per second. The vibratory forces of these devices are thought to lower mucus viscosity.

An IPV is a mechanized form of chest physical therapy, which delivers mini bursts (more than 200 per minute) of respiratory gases to the lungs via a mouthpiece. Its purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, delivery rates and peak pressure. Alternatively, a therapist will do a slapping or clapping of the patient's chest wall.

Clinical Evidence

<u>Combination continuous positive expiratory pressure (CPEP), continuous high</u> <u>frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation</u> <u>and lung expansion (OLE)</u>

Due to insufficient quality evidence or consistency of findings, combination CPEP, CHFO, and nebulized medication therapy devices for OLE are considered unproven and not medically necessary.

Main and Rand (2023) conducted a systematic review and meta-analysis to evaluate the effectiveness (in terms of respiratory function, respiratory exacerbations, exercise capacity) and acceptability (in terms of individual preference, adherence, quality of life) of conventional chest physiotherapy (CCPT) for people with cystic fibrosis (CF) compared to alternative airway clearance techniques (ACTs). The authors included randomized or quasi-randomized controlled trials (including cross-over design) lasting at least seven days and comparing CCPT with alternative ACTs in people with CF. Primary outcomes were 1. pulmonary function tests and 2. number of respiratory exacerbations per year. Secondary outcomes were 3. quality of life, 4. adherence to therapy, 5. cost-benefit analysis, 6. objective change in exercise capacity, 7. additional lung function tests, 8. ventilation scanning, 9. blood oxygen levels, 10. nutritional status, 11. mortality, 12. mucus transport rate, and 13. mucus wet or dry weight. Outcomes were reported as short-term (seven to 20 days), medium-term (more than 20 days to up to one year) and long-term (over one year). A total of 21 (778 participants) studies comprising seven short-term, eight medium-term and six long-term studies were included. Studies were conducted in the USA (10), Canada (five), Australia (two), the UK (two), Denmark (one) and Italy (one) with a median of 23 participants per study (range 13 to 166). Participant ages ranged from newborns to 45 years; most studies only recruited children and young people. Sixteen studies reported the sex of participants (375 males; 296 females). Most studies

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compared modifications of CCPT with a single comparator, but two studies compared three interventions, and another compared four interventions. The interventions varied in the duration of treatments, times per day and periods of comparison making meta-analysis challenging. All evidence was very low certainty. Nineteen studies reported the primary outcomes forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) and found no difference in change from baseline in FEV1 % predicted or rate of decline between groups for either measure. Most studies suggested equivalence between CCPT and alternative ACTs, including positive expiratory pressure (PEP), extrapulmonary mechanical percussion, active cycle of breathing technique (ACBT), oscillating PEP devices (O-PEP), autogenic drainage (AD) and exercise. Where single studies suggested superiority of one ACT, these findings were not corroborated in similar studies; pooled data generally concluded that effects of CCPT were comparable to those of alternative ACTs. CCPT versus PEP: The authors are uncertain whether CCPT improves lung function or has an impact on the number of respiratory exacerbations per year compared with PEP (both very low-certainty evidence). There were no analyzable data for secondary outcomes, but many studies provided favorable narrative reports on the independence achieved with PEP mask therapy. CCPT versus extrapulmonary mechanical percussion: The authors are uncertain whether CCPT improves lung function compared with extrapulmonary mechanical percussions (very low-certainty evidence). The annual rate of decline in average forced expiratory flow between 25% and 75% of FVC (FEF25-75) was greater with high-frequency chest compression compared to CCPT in medium- to long-term studies, but there was no difference in any other outcome. CCPT versus ACBT: The authors are uncertain whether CCPT improves lung function compared to ACBT (very low-certainty evidence). Annual decline in FEF25-75 was worse in participants using the FET component of ACBT only (mean difference (MD) 6.00, 95% confidence interval (CI) 0.55 to 11.45; 1 study, 63 participants; very low-certainty evidence). One short-term study reported that directed coughing was as effective as CCPT for all lung function outcomes, but with no analyzable data. One study found no difference in hospital admissions and days in hospital for exacerbations. CCPT versus O-PEP: The authors are uncertain whether CCPT improves lung function compared to O-PEP devices (Flutter device and intrapulmonary percussive ventilation); however, only one study provided analyzable data (very low-certainty evidence). No study reported data for number of exacerbations. There was no difference in results for number of days in hospital for an exacerbation, number of hospital admissions and number of days of intravenous antibiotics; this was also true for other secondary outcomes. CCPT versus AD: The authors are uncertain whether CCPT improves lung function compared to AD (very low-certainty evidence). No studies reported the number of exacerbations per year; however, one study reported more hospital admissions for exacerbations in the CCPT group (MD 0.24, 95% CI 0.06 to 0.42; 33 participants). One study provided a narrative report of a preference for AD. CCPT versus exercise: The authors are uncertain whether CCPT improves lung function compared to exercise (very lowcertainty evidence). Analysis of original data from one study demonstrated a higher FEV1 % predicted (MD 7.05, 95% CI 3.15 to 10.95; P = 0.0004), FVC (MD 7.83, 95% CI 2.48 to 13.18; P = 0.004) and FEF25-75 (MD 7.05, 95% CI 3.15 to 10.95; P = 0.0004) in the CCPT group; however, the study reported no difference between groups (likely because the original analysis accounted for baseline differences). The authors concluded that they are uncertain whether CCPT has a more positive impact on respiratory function, respiratory exacerbations, individual preference, adherence, quality of life, exercise capacity and other outcomes when compared to alternative ACTs as the certainty of the evidence is very low. There was no advantage in respiratory function of CCPT over alternative ACTs, but this may reflect insufficient evidence rather than real equivalence. Narrative reports indicated that participants prefer self-administered ACTs. This review is limited by a paucity of well-designed, adequately powered, long-term studies. This review cannot yet recommend any single ACT above others; physiotherapists and people with CF may wish to try different ACTs until they find an ACT that suits them best.

Morrison and Milroy (2020) conducted a systematic review and meta-analysis to identify whether oscillatory devices, oral or chest wall, are effective for mucociliary clearance and whether they are equivalent or superior to other forms of airway clearance in the successful management of secretions in people with cystic fibrosis (CF). Search criteria included randomized controlled studies and controlled clinical studies of oscillating devices compared with any other form of physiotherapy in people with cystic fibrosis. Single-treatment interventions (therapy technique used only once in the comparison) were excluded. Two authors independently applied the inclusion criteria to publications, assessed the quality of the included studies and assessed the evidence using GRADE. The searches 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

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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 guality 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 lowguality 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. The authors concluded that 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, we 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.

Huynh et al. (2019) conducted a multicenter, non-randomized prospective study to examine the impact of oscillation and lung expansion (OLE) therapy, using continuous high-frequency oscillation and continuous positive expiratory pressure on post-operative pulmonary complications (PPCs) in high-risk patients. In stage I, CPT and ICD codes were queried for patients (n = 210) undergoing thoracic, upper abdominal, or aortic open procedures at 3 institutions from December 2014 to April 2016. Patients were selected randomly. Age, comorbidities, American Society of Anesthesiologists physical status classification scores, and PPC rates were determined. In stage II, 209 subjects were enrolled prospectively from October 2016 to July 2017 using the same criteria. Stage II subjects received OLE treatment and standard respiratory care. The PPCs rate (prolonged ventilation, high-level respiratory support, pneumonia, ICU readmission) were compared. The authors also compared ICU length of stay (LOS), hospital LOS, and mortality using t-tests and analysis of covariance. Data are mean \pm SD. There were 419 subjects. Stage II patients were older (61.1 \pm 13.7 years vs 57.4 \pm 15.5 years; p < 0.05) and had higher American Society of Anesthesiologists scores. Treatment with OLE decreased PPCs from 22.9% (stage I) to 15.8% (stage II) (p < 0.01 adjusted for age, American Society of Anesthesiologists score, and operation time). Similarly, OLE treatment reduced ventilator time (23.7 \pm 107.5 hours to 8.5 \pm 27.5 hours; p < 0.05) and hospital LOS (8.4 \pm 7.9 days to 6.8 \pm 5.0 days; p < 0.05). No differences in ICU LOS, pneumonia, or mortality were observed. The authors concluded that aggressive treatment with OLE reduces PPCs and resource use in high-risk surgical patients. Well designed, adequately powered, prospective, controlled clinical trials of combination OLE treatment are needed to further describe safety and clinical efficacy.

Intrapulmonary Percussive Ventilation (IPV)

There is insufficient quality evidence or consistency of findings to support the long-term home use of intrapulmonary percussive ventilation devices.

Hassan et al. (2021) conducted a retrospective pilot study to evaluate the safety and feasibility of intrapulmonary percussive ventilation (IPV) intervention in non-intubated patients admitted to an intensive care unit. The medical records of 35 subjects were reviewed, including 22 subjects who received IPV intervention, and 13 subjects matched for age, sex, and primary diagnosis who received chest physiotherapy (CPT). The records were audited

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for feasibility, safety, changes in oxygen saturation, chest X-ray changes, and intensive care unit length of stay. A total of 104 treatment sessions (IPV 65 and CPT 39) were delivered to subjects admitted with a range of respiratory conditions in critical care. Subjects completed 97% of IPV sessions. No major adverse events were reported with intrapulmonary percussive ventilation intervention. Intensive care unit length of stay in the intrapulmonary percussive ventilation group was 9.6 ± 6 days, and in the CPT group, it was 11 ± 9 days (p = 0.59). Peripheral oxygen saturation pre to post intervention was $92\% \pm 4$ to $96\% \pm 4$ in IPV group and $95\% \pm 4$ to $95\% \pm 3$ in the CPT group. The authors concluded that application of IPV intervention was feasible and safe in spontaneously breathing non-intubated adult patients in critical care. The study is limited by its retrospective observations. There is a need for an adequately powered randomized controlled trial (RCT) to further evaluate the effects of IPV intervention in a non-intubated population in critical care.

Hassan et al. (2021) performed a systematic review to summarize the evidence of the effectiveness of intrapulmonary percussive ventilation (IPV) on intensive care unit length of stay (ICU-LOS) and respiratory outcomes in critically ill patients. A systematic search of IPV in intensive care units (ICU) was performed on five databases from 1979 to 2021. Studies were considered for inclusion if they evaluated the effectiveness of IPV in patients aged ≥16 years receiving invasive or non-invasive ventilation or breathing spontaneously in critical care or high dependency units. Study titles and abstracts were screened, followed by data extraction by a full-text review. Due to a small number of studies and observed heterogeneities in the study methodology and patient population, a meta-analysis could not be included in this review. Out of 306 identified abstracts, seven studies (630 patients) met the eligibility criteria. Results of the included studies provide weak evidence to support the effectiveness of IPV in reducing ICU-LOS, improving gas exchange, and reducing respiratory rate. The authors concluded that based on the findings of this review, the evidence to support the role of IPV in reducing ICU-LOS, improving gas exchange, and reducing respiratory rate is weak. The therapeutic value of IPV in airway clearance, preventing pneumonia, and treating pulmonary atelectasis requires further investigation. This study has several limitations. The number of studies retrieved was small (7). Heterogeneities resulting from differences in study design, patient population, dosage, and frequency of IPV intervention were frequently observed in the included studies. Further, small sample sizes and poor methodological quality introduces some bias and weakens the strength of conclusions of this review. Further investigation is needed before clinical usefulness of this procedure is proven.

Nicolini et al. (2018) conducted a four-week RCT to determine if adding Intrapulmonary percussive ventilation (IPV) or high-frequency chest wall oscillation (HFCWO) with the best pharmacological therapy (PT) will provide clinical benefit to patients with chronic obstructive pulmonary disease (COPD) over just chest physiotherapy (CPT). There was a total of 63 patients randomized into three groups (20 patients completed the trial in each group): IPV group (treated with PT and IPV), PT group with (treated with PT and HFCWO), and control group (treated with PT alone). Primary outcomes measured are the dyspnea scale ([modified Medical Research Council [(mMRC])] and Breathlessness, Cough, and Sputum scale (BCSS), along with daily life activity ([COPD Assessment Test [(CAT]).)]. Secondary outcomes measured are pulmonary function testing (PFT), arterial blood gas analysis, and hematological examinations. Patients in both the IPV and HFCWO group showed marked improvement in dyspnea and mMRC, BCSS and CAT compared to the control group. IPV patients showed an improvement in BCSS (p = 0.001) and CAT (p = 0.02) scores in comparison with HFCWO. Both IPV and HFCWO secondary outcomes improved compared to the control group. In the group comparison analysis of the IPV group and HFCWO group variables, there was marked improvement in the IPV group in total lung capacity (TLC) and TLC% (p = 0.03), residual volume (RV) and RV% (p = 0.04), and diffusing lung capacity monoxide (DLCO), maximal inspiratory pressure (MIP), and maximal lung capacity (MEP, p = 0.01). The authors concluded that both IPV and HFCWO can improve lung function, muscular strength, dyspnea and overall health status. and that IPV demonstrated better effectiveness in improving test results in small bronchial airways and alveolar ventilation (RV and DLCO) and muscular strength (MIP and MEP) as well as scores on daily life activity and health status assessment scales (BCSS and CAT) compared with HFCWO. A multi-center, larger population study with measurement of primary and secondary outcomes over a longer term is needed. Limitations of this study included single center, small sample size, and short duration and lack of masking or sham procedure. Furthermore, the intervention was delivered by a physical therapist; therefore, these findings may not be generalizable to IPV used at home and without professional supervision or for conditions other than COPD.

Reychler et al. (2018) conducted a systematic review to summarize the physiological and clinical effects related to the use of IPV as an airway clearance technique in chronic obstructive airway diseases. Using predetermined criteria, a search

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was conducted in PubMed, PEDro, and Scopus online databases. Outcomes of interest included immediate or prolonged physiological effects (e.g., gas exchange, cardiorespiratory parameters, lung function, and mechanics) and clinical effects (e.g., symptoms, adverse effects, and length of hospital stay). A total of 109 studies were identified and after further evaluation, 12 studies were included in the review. Of those, 1 study evaluated patients with bronchiectasis (n = 22), 4 studies evaluated patients with cystic fibrosis (n = 78), and 6 studies (1 study included phase I and 2 results) evaluated patients with COPD (n = 178). In patients with COPD, IPV improved gas exchange during exacerbation and reduced the hospital length of stay however, IPV was no more beneficial than other airway clearance techniques when subjects were stable. Two studies reported complications or discomfort with IPV and in another study, 2 patients did not tolerate settings with a higher frequency of percussions (1.220 cm H2O-350 c/min and 1.840 cm H2O-350 c/min). In patients with CF, cardiorespiratory parameters and lung function did not improve with IPV. One study reported mild hemoptysis, which was associated with a respiratory infection. In patients with bronchiectasis, dyspnea and respiratory frequency improved after 1 session of IPV however, there was no difference in sputum dry weight and in patients with productive bronchiectasis, immediate efficacy of IPV vs. other airway clearance techniques did not differ. Minor adverse events (dry throat, nausea, and/or fatigue) were reported in 27% of patients treated with both IVP and chest physical therapy. The authors concluded that use of IPV as an airway clearance technique in chronic obstructive airway diseases is not supported by sufficiently strong evidence to recommend routine use in this patient population.

Professional SocietiesClinical Practice Guidelines

<u>American Academy of Neurology (AAN)</u>

An AAN practice parameter states that there is insufficient data to support or refute HFCWC for clearing airway secretions in patients with ALS (Miller et al., 2009).

American College of Chest Physicians (ACCP)

Hill et al. (2018) conducted a systematic review on airway clearance in bronchiectasis due to cystic fibrosis (CF) and other causes by using non-pharmacological methods as recommended by international guidelines to develop recommendations or suggestions to update the 2006 CHEST guideline on cough. The systematic search for evidence examined the question, "Is there evidence of clinically important treatment effects for non-pharmacological therapies in cough treatment for patients with bronchiectasis?" Populations selected were all patients with bronchiectasis due to CF or non-CF bronchiectasis. The interventions explored were the non-pharmacological airway clearance therapies. The comparison populations included those receiving standard therapy and/or placebo. Clinically important outcomes that were explored were exacerbation rates, quality of life, hospitalizations, and mortality. In both CF and non-CF bronchiectasis, there were systematic reviews and overviews of systematic reviews identified. Despite these findings, there were no large randomized controlled trials (RCTs) that explored the impact of airway clearance on exacerbation rates, quality of life, hospitalizations, or mortality. The authors concluded there is insufficient evidence that any airway clearance technique is consistently more effective than any other for clinically important outcomes in CF bronchiectasis.

American Thoracic Society (ATS)

In a consensus statement on the respiratory care of patients with Duchenne muscular dystrophy (DMD), the ATS states that effective airway clearance is critical for patients with DMD to prevent atelectasis and pneumonia. Ineffective airway clearance can hasten the onset of respiratory failure and death, whereas early intervention to improve airway clearance can prevent hospitalization and reduce the incidence of pneumonia. HFCWC 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. Patients with DMD should be taught strategies to improve airway clearance and how to employ those techniques early and aggressively.

ATS makes the following recommendations:

- 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 <u>60 cm H20</u>
- The committee strongly supports use of mechanical insufflation-exsufflation in patients with DMD and also
 recommends further studies of this modality

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Home pulse oximetry is useful to monitor the effectiveness of airway clearance during respiratory illnesses and to identify patients with DMD needing hospitalization (Finder et al., 2004)

National Institute for Health and Care Excellence (NICE)

In a 2018 MedTech innovation briefing, the National Institute for Health and Care Excellence (NICE) found no published guidelines on airway clearance in people with complex neurological needs.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

High-Frequency Chest Wall Compression Devices

High-frequency chest wall compression devices are designed to promote airway clearance and improve bronchial drainage. They are indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport. Refer to the following website for more information (use product code BYI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 1826, 20243)

References

Hassan A, Lai W, Alison J, et al. Effect of intrapulmonary percussive ventilation on intensive care unit length of stay, the incidence of pneumonia and gas exchange in critically ill patients: A systematic review. PLoS One. 2021 Jul 28;16(7):e0255005.

Hassan A, Milross M, Lai W, et al. Feasibility and safety of intrapulmonary percussive ventilation in spontaneously breathing, non-ventilated patients in critical care: A retrospective pilot study. J Intensive Care Soc. 2021 May;22(2):111-119.

Hill AT, Barker AF, Bolser DC, et al. Treating cough due to non-CF and CF bronchiectasis with nonpharmacological airway clearance: CHEST expert panel report. Chest. 2018 Apr;153(4):986-993.

Huynh TT, Liesching TN, Cereda M, et al. Efficacy of oscillation and lung expansion in reducing postoperative pulmonary complication. J Am Coll Surg. 2019 Nov;229(5):458-466.e1.

Louisiana Department of Health: Durable Medical Equipment Provider Manual, Section 18.2 – High Frequency Chest Wall Oscillation Devices of the Medicaid Services Manual:

https://www.lamedicaid.com/provweb1/providermanuals/manuals/DME/DME.pdf. Accessed November 13, 20243.

Main E, Rand S. Conventional chest physiotherapy compared to other airway clearance techniques for cystic fibrosis. Cochrane Database Syst Rev. 2023 May 5;5(5):CD002011.

Morrison L, Milroy S. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2020 Apr 30;4(4):CD006842.

National Institute for Health and Care Excellence (NICE). The Vest for delivering high-frequency chest wall oscillation in people with complex neurological needs. Medtech innovation briefing [MIB159] Published date: September 2018.

Nicolini A, Grecchi B, Ferrari-Bravo M, et al. Safety and effectiveness of the high-frequency chest wall oscillation vs intrapulmonary percussive ventilation in patients with severe COPD. Int J Chron Obstruct Pulmon Dis. 2018 Feb 16;13:617-625.

Reychler G, Debier E, Contal O, et al. Intrapulmonary percussive ventilation as an airway clearance technique in subjects with chronic obstructive airway diseases. Respir Care. 2018 May;63(5):620-631.

Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	Coverage Rationale
	Non State-Specific Criteria
	 Added language to indicate combination continuous positive expiratory pressure
	(CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy
	devices for oscillation and lung expansion (OLE) are considered unproven and not
	medically necessary
	Applicable Codes
	Added HCPCS codes A7021 and E0469
	 Added notation to indicate HCPCS codes A7021 and E0469 are not on the State of
	Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of
	Louisiana Medicaid Program
	Supporting Information
	 Updated Clinical Evidence and References sections to reflect the most current
	information
	<u>Archived previous policy version CS054LA1.D</u>

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.