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Airway Clearance Devices (for Louisiana Only)

Policy Number: CS054LA1.~~ED~~

Effective Date: ~~April 1, 2023~~**TBD**

[Instructions for Use](#)

Certain ~~e~~content mandated by Louisiana Department of Health

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Application

This Medical Policy only applies to the state of Louisiana. Portions of ~~t~~the coverage rationale contained in this policy represents Louisiana Medicaid coverage policy and are ~~is~~ set forth below in accordance with s~~st~~ate requirements.

Coverage Rationale

State Specific Criteria

High frequency chest wall oscillation devices (E0483) are covered for beneficiaries who meet the following criteria~~criteria~~^[MEA2].

The beneficiary must have one of the following:

- A diagnosis of cystic fibrosis
- 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
 - Confirmed by high resolution, spiral, or standard CT scan
- 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

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Non-State Specific Criteria

Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not medically necessary^[MEA3].

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
*A7025	High frequency chest wall oscillation system vest, replacement for use with patient- owned ^[MEA4] equipment, each
*A7026	High frequency chest wall oscillation system hose, replacement for use with patient- owned equipment, each
*E0481	Intrapulmonary percussive ventilation system and related ^[MEA5] 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, ^[MEA6] 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
G12.21	Amyotrophic lateral sclerosis

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Diagnosis Code	Description
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

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Diagnosis Code	Description
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 [MEA7]

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.

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

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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 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 IPV 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.

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Professional Societies

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.

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 ~~July 28, 2022~~ **September 26, 2023**)

References

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.

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 ~~October 18, 2022~~ **November 1, 2023**.

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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>	<u>Application</u> <ul style="list-style-type: none">Added language to clarify portions of the Coverage Rationale contained in this policy represents Louisiana Medicaid coverage policy and are set forth [in the policy] in accordance with State requirements <u>Coverage Rationale</u> <u>Non State-Specific Criteria</u> <ul style="list-style-type: none">Added language to indicate intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not medically necessary <u>Applicable Codes</u> <ul style="list-style-type: none">Revised description for HCPCS code E0483 <u>Supporting Information</u> <ul style="list-style-type: none">Added Definitions and Clinical Evidence sectionsUpdated References section to reflect the most current information <u>Archived previous policy version CS054LA1.C</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.

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