Guidelines for Medical Necessity Determination for High Frequency Chest Wall Oscillation Air-Pulse Generator System (Vest)

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for a High Frequency Chest Wall Oscillation Air-Pulse Generator System (Vest). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 427.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, Subchapter 6 of the *Oxygen and Respiratory Therapy Equipment (*OXY) *Manual* and the online *MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guideline Tool* for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Links to the regulations, subchapter 6, the tool, and the referenced prior authorization form can be found in the appendix.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care Organization, Senior Care Organization (SCO), or a Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for a High Frequency Chest Wall Oscillation Air-Pulse Generator System (Vest). MassHealth reviews requests for PA on the basis of medical necessity. Prior authorization determines only the medical necessity of the authorized item or service. Payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program limitations.

SECTION I. GENERAL INFORMATION

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Patients with certain conditions, such as those with cystic fibrosis (CF), bronchiectasis, and some neurologic and neuromuscular disorders, those with and those at risk for compromised ability to actively clear secretions from the respiratory tract and increased risk for pneumonia or other respiratory complications. Patients receive treatments to assist with Airway Clearance Therapy (ACT) including chest physiotherapy (CPT) that utilizes manual percussion and vibration of the chest to loosen the secretions. High frequency chest wall oscillation (HFCWO) devices are considered when conventional and/or conservative ACT measures have failed.

HFCWO devices deliver compression pulses to the chest wall through an inflatable vest, which is connected to an air pulse generator. These high frequency compressions lead to changes in airway volume and flow, which helps to loosen and mobilize secretions to the large airways for removal by a

strong, effective cough or suctioning procedure. Each typical treatment performed at home lasts 20–30 minutes and consists of short periods (approximately 5 minutes) of vest compression followed by coughing.

U.S. Food and Drug Administration (FDA)-cleared High Frequency Chest Compression (HFCC) devices, such as the Vest Airway Clearance System, (Hill-Rom, St. Paul, MN; previously manufactured by Advanced Respiratory, Inc., St. Paul, MN), the SmartVest Airway Clearance System (Electromed, Inc., New Prague, MN), the inCourage™ System (RespirTech, Inc., St. Paul, MN), Electro Flo® Airway Clearance System (Med Systems, Inc., White River Junction, VT) and the Medpulse Respiratory Vest System (Electromed, Inc., Minnetonka, MN), are alternative therapy for selected individuals described below; PA for these services should be submitted by a MassHealth provider of Oxygen and Respiratory Therapy Equipment.

SECTION II. CLINICAL GUIDELINES

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A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for a Vest on clinical data including, but not limited to, indicators that would affect the relative medical risks and benefits of a Vest. These criteria include, but are not limited to, the following:

1. The member has at least one of the following conditions:
    a. A diagnosis of cystic fibrosis; or
    b. A diagnosis of bronchiectasis AND the following criteria are met:
        i. Diagnosis is confirmed by a high resolution, spiral, or standard CT scan of the chest; –**AND**-
        ii. The Member has had daily productive cough for at least 6 continuous months; –**OR**-
        iii. The Member has had frequent (more than 2 per year) exacerbations requiring antibiotic and mechanical airway clearance therapy
    c. A diagnosis of a neuromuscular disease that affects the ability to cough or clear respiratory secretions including but not limited to:
        i. Acid maltase deficiency;
        ii. Anterior Horn Cell Diseases;
        iii. Hereditary Muscular Dystrophy;
        iv. Multiple Sclerosis;
        v. Myotonic Disorders;
        vi. Paralysis of the Diaphragm;
        vii. Post-polio syndrome;
        viii. Quadriplegia; or
        ix. Other myopathies.

2. The member does not have an absolute contraindication to Vest device use and relative contraindications have been fully addressed by a medical provider.

    a. Absolute contraindications are:

        i. Unstable head or neck injury; or

        ii. Active hemorrhage with hemodynamic instability.

    b. Relative contraindications are:

        i. Lung contusion;

        ii. Osteomyelitis of the ribs;

        iii. Rib fracture;

        iv. Osteoporosis;

        v. Coagulopathy; or

        vi. Presence of chest wall pain.

3. There is well-documented failure of standard treatment for clearance and mobilization of retained secretions including but not limited to:

    a. Suction machine;

    b. Cough assist with cough track technology;

    c. Manual chest physiotherapy (CPT);

    d. Manual or electric percussor ;

    e. Positive Expiratory Pressure (PEP) devices or flutter values; or

    f. Inhaled Mucolytics.

4. There is well-documented lack of caregiver ability to perform CPT at required frequency resulting in recurrent infection or hospitalization related to the underlying disease.

B. NONCOVERAGE

MassHealth does not consider a Vest to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following:

1. Chronic lung disease, including chronic bronchitis and chronic obstructive pulmonary disease (COPD), in the absence of confirmed diagnosis of bronchiectasis

2. Manual CPT or other less costly and effective therapies are available.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

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A. Requests for prior authorization for a Vest must be accompanied by clinical documentation, as described below, that supports the medical necessity for a Vest and must be submitted to MassHealth in accordance with the *MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guideline Tool*. As part of the PA request, the provider of Oxygen and Respiratory Therapy Equipment must obtain a written prescription and letter of medical necessity signed by the member's ordering practitioner. The prescription and letter of medical necessity must meet the requirements of **130 CMR 427.408**. Any additional clinical documentation supporting medical necessity must be submitted with the prior authorization request and must meet the requirements of **130 CMR 450.204 and 450.303**.

B. Documentation of medical necessity must include all of the following:

   1. Prescribing provider documentation of a qualifying diagnosis.
   2. Additional documentation supporting the PA request, including, but not limited to documentation of:
      a. History of impaired mucus clearance and unmanageable secretions;
      b. Use and failure of standard airway clearance options;
      c. Use and failure of other treatment modalities (i.e., pharmacologic agents including inhaled antibiotic regimen, mucolytic agents, and expectorants);
      d. Frequency of antibiotic use in the previous year;
      e. Sputum sample laboratory results from the previous 3 months;
      f. Evidence suggesting member demonstrates strong enough cough to expectorate secretions; and
      g. Documentation that member has trialed a Vest device, which includes documentation of breath sounds before, during and after Vest therapy; cough assessment; member tolerance of trial and therapeutic settings; and Physical Therapy Evaluation of a Vest trial.

Oxygen and Respiratory Therapy Equipment providers are encouraged to submit requests electronically, submitting all information related to the PA request through the Long-Term Services and Supports (LTSS) Management System (LTMS). If submitting a non-electronic request, an Oxygen and Respiratory Therapy Equipment provider should mail the PA-1 form, and any supporting documentation, to the address on the back of the PA-1 form. Oxygen and Respiratory Therapy Equipment providers with any questions about LTMS access may direct them to the MassHealth LTSS Provider Service Center, at 1-844-368-5184. The link for the PA-1 form is below.

When submitting PA requests for Community Case Management (CCM) members, Oxygen and Respiratory Therapy Equipment providers must submit all information related to the PA request through the Provider Online Service Center (POSC). If submitting a non-electronic request, the provider should mail the PA-1 form, and any supporting documentation, to the address on the back of the PA-1 form. Providers with any questions about POSC access may direct them to the MassHealth Customer Service Center, at (800) 841-2900.

APPENDIX:

Code	Description	Limits*
E0483	High frequency chest wall oscillation air pulse generator system, includes all accessories and supplies, each.	1 unit = each, 1 per 5 years
A7025	High frequency chest wall oscillation system *vest*, replacement for use with patient owned equipment, each	1 unit = each, 1 per 3 years.
A7026	High frequency chest wall oscillation system *hose*, replacement for use with patient owned equipment, each.	1 unit = each, 1 per 3 years.

*Note that providers may seek PA for items at a frequency shorter than the otherwise applicable limit pursuant to Subchapter 6, Section 601 of the *MassHealth Oxygen and Respiratory Therapy Equipment Manual*.

130 CMR 409.000: Durable Medical Equipment Services: https://www.mass.gov/regulations/130-CMR-409000-durable-medical-equipment-services

MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guideline Tool:https://www.mass.gov/info-details/masshealth-payment-and-coverage-guideline-tools#masshealth-durable-medical-equipment-and-oxygen-payment-and-coverage-guideline-tool-

Subchapter 6: Oxygen and Respiratory Therapy Equipment Service Codes: https://www.mass.gov/lists/oxygen-and-respiratory-therapy-equipment-manual-for-masshealth-providers#subchapter-6:-oxygen-and-respiratory-therapy-equipment-service-codes-

130 CMR 450.00: Administrative and billing regulations: https://www.mass.gov/regulations/130-CMR-45000-administrative-and-billing-regulations

MassHealth Oxygen and Respiratory Therapy Equipment PA-1 form: https://www.mass.gov/doc/prior-authorization-request-pa-1/download

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These Guidelines are based on review of the medical literature and current standards of care in the use of High Frequency Chest Wall Oscillation Air-Pulse Generator System (Vest). MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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