MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

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REVISION DATE: 03/15
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SUBJECT: High Frequency Chest Wall Oscillation Devices
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2013

This policy applies to the following lines of business: (Check those that apply.)

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<th>COMMERCIAL</th>
<th>[ ] HMO</th>
<th>[ ] PPO</th>
<th>[ ] Fully Insured</th>
<th>[ ] Individual Product</th>
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<td>GOVERNMENT PROGRAMS</td>
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| OTHER            | [ X ] Self-funded/ASO

I. POLICY

It is the policy of MedStar Health, Inc. to cover high frequency chest wall oscillation devices (HFCWO) as a Durable Medical Equipment benefit under the capped rental plan when it is medically necessary and covered under the member’s specific benefit plan. Coverage will be considered, after review on an individual basis, for the specific indications detailed in this policy.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

For repairs and replacement information, refer to the Durable Medical Equipment and Corrective Appliances policy.

II. DEFINITIONS

Bronchiectasis is defined as an irreversible dilatation and destruction of bronchi with a reduction in clearance of secretions (and particularly in the expiratory airflow). The disease can lead to recurrent lower respiratory tract infections and worsening pulmonary function, with increased morbidity and mortality.

High Frequency Chest Wall Oscillation Device (HFCWO) (also known as high-frequency chest compression (HFCC)) is a non-pharmacologic method designed to deliver effective and well-tolerated airway clearance treatment.
HFCWO are also known as High Frequency Chest Compression (HFCC) Devices. (Some examples are: ThAIRapy Vest, The Vest ™, SmartVest, Hill-Rom Vest).

III. PURPOSE

The purpose of this policy is to identify the coverage criteria for use of the high frequency chest wall oscillation devices (HFCWO).

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description

High Frequency Chest Wall Oscillation Devices (HFCWO) High-frequency chest wall oscillation devices (HFCWO) devices assist members who have difficulty expelling bronchial secretions, essentially the same population of members requiring postural drainage (drainage of the middle and large airways). These members are especially prone to secretion-related complications during upper respiratory tract infections or general anesthesia.

HFCWO works under the theory that compression of the chest will induce airflow that dislodges mucus adherent to the bronchial walls. These devices consist of a high-frequency chest wall oscillator designed to enhance the mobilization of bronchial secretions. In some portions of the lung, airflows can be nearly or totally blocked by mucus plugs. The oscillating pressure pulse could move the plugs toward large-diameter airways, where they can be cleared more easily. Additional theories propose the triggering of thin mucus production, airway-dilating nitric oxide production, and higher air-outflow rates compared to inflow rates.

HFCWO systems consist of two main components: a vest worn by the patient and a pneumatic air-pulse generator that rapidly inflates and deflates the vest.
The vest is made of non-stretch material and covers the thorax like a life jacket; two large-bore air hoses connect the vest to the generator. A hand/foot control can be used to start or stop the compression.

B. Specific Indications

INITIAL REVIEW
A high frequency chest wall oscillation device (HFCWO) is considered medically necessary when the member meets all of the following:
1. The member has failed trials of alternative methods of expectoration (i.e. mucolytic agents, handheld flutter device, self-controlled breathing techniques, conventional chest physical therapy consisting of postural drainage and percussion)
   AND
2. The member has an adequate physiological cough reflex.
   AND
3. The member has one of the following conditions:
   • Cystic fibrosis
   Or
   • One of the following:
     o Bronchiectasis which has been confirmed by a high resolution, spiral, or standard computed tomography (CT) scan and which is characterized by:
       o Daily productive for at least six continuous months; or
       • Frequent (i.e. more than two year) exacerbations requiring antibiotic therapy
     o Ciliary dyskinesia syndrome
     o Cavitating lung disease
     o Other chronic conditions including but not limited to:
       • Post-polio
       • Acid maltase deficiency
       • Anterior horn cell diseases
       • Multiple sclerosis
       • Quadriplegia
       • Hereditary muscular dystrophy
       • Myotonic disorders
       • Other myopathies
       • Paralysis of the diaphragm

CONTINUATION OF HCFWO:
Successful rental trials for three months need to be documented prior to extensions.
Replacement supplies
Replacement supplies are covered when the criteria for the base device are met.

C. Limitations/Exclusions include all of the following:

1. **Absolute contraindications** include the following:
   - Unstabilized head or neck injury
   - Active hemorrhage with hemodynamic instability
   - Acute respiratory distress/failure.

2. **Relative contraindications** include the following:
   - Subcutaneous emphysema (gas within the tissue beneath the skin),
   - Recent epidural spinal infusion or spinal anesthesia
   - Recent placement of an indwelling venous catheter in the chest wall
   - Intravenous access to an indwelling venous catheter (members with established port sites can receive HFCWO if the sites are covered with padding.)
   - Recent skin grafts or flaps on the thorax
   - Burns, open wounds, or skin infections of the thorax
   - Recently placed transvenous or subcutaneous pacemaker or any device implanted in the chest or chest wall
   - Suspected pulmonary tuberculosis
   - Recent abdominal surgery
   - Recent gastrostomy tube placement
   - Lung contusion
   - Rib fractures
   - Acute bronchospasm
   - Chest wall pain
   - Osteomyelitis of the ribs
   - Osteoporosis
   - Coagulopathy

**Exclusions – HFCWO devices are considered** not medically necessary and therefore not covered for the following:
   - Chronic bronchitis and chronic obstructive pulmonary disease (COPD) in the absence of a confirmed diagnosis of bronchiectasis
   - The use of a HFCWO and a mechanical insufflation device at the same time.
   - Use of devices that are not approved by the Food and Drug Administration (FDA) or have been recalled by the FDA
D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating physician. Necessary information includes the following:

1. A physician’s prescription or letter of medical necessity.
2. Documentation supporting the member’s need for the HFCWO that includes:
   - The member’s diagnosis
   - Information related to the disease process supporting the medical necessity of the device. This includes the results of a CT scan for those members with a diagnosis of bronchiectasis
   - Information that the member has failed trials of alternative methods of expectoration (i.e. mucolytic agents, handheld flutter device, self-controlled breathing techniques, conventional chest physical therapy consisting of postural drainage and percussion)
   - Complete history to rule out any contraindications
   - Rental trials of the HFCWO were attempted.
   Note: Successful rental trials for three months need to be documented prior to extensions.

E. Review Process

1. The Medical Management staff assigned to review obtains the clinical information, to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member’s benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure for Records Retention.

H. Codes
The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable HCPCS/CPT codes:

E0483  High frequency chest wall oscillation air-pulse generator system, (includes hose and vest), each

I. References

Medical Literature/Clinical Information:


Regulatory/Government Source:

Disclaimer:

MedStar Health, Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health, Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health, Inc. reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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