blue of california

Medical Policy

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Diseases	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Durable Medical Equipment
Original Policy Date: December 1, 2004	**Effective Date:** September 27, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Respiratory disorders characterized by excessive tenacious secretions and impaired airway clearance, such as cystic fibrosis and bronchiectasis, can result in the inability of the patient to clear mucus from their airways effectively. Oscillatory devices are used as alternatives to the

standard daily percussion and postural drainage (P/PD) method of airway clearance, also known as chest physiotherapy, for these patients. There are several types of devices including high-frequency chest compression (HFCW) with an inflatable vest and oscillating positive expiratory pressure (PEP) devices, (e.g., the Flutter and Acapella devices). Oscillatory devices are also proposed for other respiratory conditions such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

Note: This policy addresses outpatient use of oscillatory devices. Inpatient device use (e.g., in the immediate post-surgical period), is not included in this policy.

Policy

Use of the Flutter® valve or Acapella® device may be considered **medically necessary** in patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.

High-frequency chest wall (HFCW) compression devices and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** in the outpatient setting when there is a demonstrated need for airway clearance, and standard chest physiotherapy has failed, is unavailable or is not tolerated and **one** of the following:

- Cystic Fibrosis
- Chronic diffuse bronchiectasis (see Policy Guideline) and **all** of the following:
    - Confirmation by high resolution or spiral chest computed tomography (CT) scan
    - Documented failure of standard treatment including **one** of the following:
        - Documentation of frequent exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physiotherapy and, if appropriate, use of the Flutter device)
        - Documentation of valid reasons why standard chest physiotherapy cannot be performed, unavailable, or is not tolerated (e.g., inability of the caregiver to perform it)

HFCW compression devices and IPV devices are considered **not medically necessary** in the outpatient setting as an alternative to chest physical therapy in patients with cystic fibrosis or bronchiectasis if the above criteria are not met.

All other indications for HFCW compression devices and IPV devices are considered **investigational** in the outpatient setting including, but not limited to, their use as an adjunct to chest physical therapy, or their use in other lung diseases, such as chronic obstructive pulmonary disease.

Policy Guideline

For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months or more than 2 times per year exacerbations requiring antibiotic therapy and confirmed by high-resolution or spiral chest computed tomography scan.

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Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process including the following:

- Oscillatory Positive Expiratory Pressure (Active Devices):
  - FLUTTER® mucus clearance device (Axcan Scandipharm Inc., Birmingham, AL)
  - Acapella® Vibratory PEP Therapy System (DHD Healthcare, Wampsville, NY)
  - RC-Cornet Mucus Clearing Device (PARI Respiratory Equipment, Inc., Midlothian, VA)
- High-Frequency Chest Wall Compression (Passive Devices):
  - The Vest® Airway Clearance System (Hill-Rom Services, Inc., St. Paul, MN) - formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System.
- Intrapulmonary Percussive Ventilation
  - Intrapulmonary Percussive Ventilation (IPV) devices (Percussionaire Corp., Sandpoint, ID).

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• History and physical from prescribing MD including: o Previous treatment plan(s) and response(s) • CT scan results to confirm bronchiectasis • Documentation of reasons why airway clearance cannot be performed, unavailable, or is not tolerated • Documentation of frequent exacerbations of respiratory distress

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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