Medical Policy Reference Manual
Medical Policy

1.01.012 Oscillatory Devices for the Treatment of Respiratory Diseases

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Description

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for patients with conditions that impair respiratory clearance. There are several types of devices including high-frequency chest compression with an inflatable vest and oscillating positive expiratory pressure devices, such as the FLUTTER® and Acapella® devices. Oscillatory devices can be useful for airway clearance in a wide variety of diseases and conditions, for example, cystic fibrosis, diffuse bronchiectasis, COPD, and in patients with neuromuscular diseases, such as multiple sclerosis and quadriplegia.

Oscillatory devices are designed to move mucus and clear airways: the oscillatory component can be intra-thoracic or extra-thoracic. Some devices require the active participation of the patient. These include oscillating positive expiratory pressure devices, such as FLUTTER® and Acapella®, in which the patient exhales multiple times through a device. The FLUTTER® device is a small pipe-shaped, easily portable hand-held device, with a mouthpiece at one end. It contains a high-density stainless-steel ball that rests in a plastic circular cone. During exhalation, the steel ball moves up and down, creating oscillations in expiratory pressure and airflow. When the oscillation frequency approximates the resonance frequency of the pulmonary system, vibration of the airways occurs, resulting in loosening of mucus. The Acapella® device is similar in concept but uses a counterweight plug and magnet to create air flow oscillation.

The high frequency chest wall oscillation vest is a passive oscillatory device designed to facilitate clearance of mucous secretions from the respiratory tract. The Vest® Airway Clearance System provides high-frequency chest compression using an inflatable vest and an air-pulse generator. Large-bore tubing connects the vest to the air-pulse generator. The air-pulse generator creates pressure pulses that cause the vest to inflate and deflate against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

The Percussionaire® device delivers intrapulmonary percussive ventilation (IPV) and is another type of passive oscillatory device. This device combines internal thoracic percussion through rapid mini bursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

Effective airway clearance therapy is essential for these patients in order to prevent infection and maintain appropriate gas exchange.

Policy

Use of the FLUTTER® valve, the Acapella® device, high frequency chest wall oscillation devices, and intrapulmonary percussive ventilation devices may be considered **medically necessary** in any disease process where clearance of pulmonary secretions is impaired. Physiologically, this could be due to increased production of secretions, impaired mucociliary clearance, the increased tendency for secretions to become inspissated, or the impaired ability of chest wall musculature to effectively aid in the cough-assist/secretion mobilization process, as seen in various neuromuscular diseases and genetic conditions where chest wall musculature is weakened and/or not well coordinated to produce an effective cough.

The device should be recommended by or prescribed by a pulmonary specialist.

High frequency chest wall oscillation devices and intrapulmonary percussive ventilation devices are considered **experimental/investigational** for all other conditions as they do not meet TEC criteria # 2-5.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association Technology Evaluation Center (TEC) are deemed to be experimental/investigational:

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* Technology includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies.

Several airway clearance devices have been cleared by the FDA via the 510(k)-approval process.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

Insufficient scientific evidence exists to permit conclusions regarding the use of high frequency chest wall oscillation devices and intrapulmonary percussive ventilation devices for indications beyond those considered medically necessary in this policy.

3. The technology must improve the net health outcome.

For conditions in which use of airway clearance devices is not considered medically necessary there is insufficient evidence that the technology improves the net health outcome.

4. The technology must be as beneficial as any established alternatives.

There is a lack of research comparing high frequency chest wall oscillation devices and percussive ventilation devices to established alternatives. Therefore, it is not possible to determine whether such devices are as effective as established alternatives.

5. The technology must be attainable outside the investigation settings.

A net health outcomes improvement has not been demonstrated in the investigational settings. Therefore, it is not possible to determine whether an improvement outside of the investigational setting can be expected.

Update 2022:

A search of literature was performed from June 2021 through February 2022. The medically necessary indications for oscillatory devices for the treatment of disease are unchanged.

Update 2021:

At the May 27, 2021 Technology Assessment Committee meeting a decision was made to expand indications for high frequency chest wall oscillation devices to include neuromuscular conditions when medically appropriate. The policy statement has been updated to reflect the intent of this policy more accurately.

Update 2019:

A search of peer-reviewed literature was performed from August 2016 through January 2019. The medically necessary indications for oscillatory devices for the treatment of cystic fibrosis and other respiratory disorders have been updated based on the current peer-reviewed literature.

Update 2016:
A search of peer-reviewed literature was performed from July 2014 through July 2016. The medically necessary indications for oscillatory devices for the treatment of cystic fibrosis and other respiratory disorders remain as outlined in the policy statement. Therefore, the policy statement is unchanged.

Update 2014:
A search of peer-reviewed literature was performed from December 2013 through June 2014. The medically necessary indications for oscillatory devices for the treatment of cystic fibrosis and other respiratory disorders have been updated based on the current peer-reviewed literature.

Update 2013:
A search of peer-reviewed literature was performed from August 2011 through August 2013. Findings in the literature do not change the medically necessary indications for oscillatory devices for the treatment of cystic fibrosis and other respiratory disorders. Therefore, the policy is unchanged.

Update 2011:
A search of the peer-reviewed literature was performed from June 2009 through July 2011 regarding various oscillatory devices used in the treatment of cystic fibrosis and other respiratory diseases. There is limited clinical data to show that these oscillatory devices provide any additional health benefit compared to conventional chest physical therapy in situations other than those specified in the policy nor is there support that any one oscillatory device is superior to another for cystic fibrosis. Use of high-frequency chest wall compression and intrapulmonary percussive ventilation devices in other chronic pulmonary diseases, such as bronchiectasis or chronic obstructive pulmonary disease (COPD), remains investigational.

Update 2009:
A search of peer-reviewed literature was performed from November 2006 through June 2009. There continues to be insufficient evidence in the literature to support use of the high frequency chest wall oscillation vest for other than the indications outlined in the policy.

Update 2006:
The current peer-reviewed literature is insufficient to support the use of the high frequency chest wall oscillation device for other than the medically necessary indications outlined in the above Policy statement.

Rationale (2004):
The high frequency chest wall oscillation device is designed to supply percussion to the chest wall in an effort to loosen thick secretions so they can be coughed or suctioned out. The literature published to date has concentrated mainly on validation of high frequency chest compression (HFCC) delivered by the pneumatic vest as equivalent to chest physiotherapy (CPT) administered by hand particularly in patients with cystic fibrosis. There is no long-term data to show that the machine offers any advantage over CPT in terms of improved health outcomes. Despite the "possible" uses for this type of airway clearance assist machine, there have been no studies that support its use in patients with COPD, neuromuscular disorders, or bronchiectasis.

Benefit Applications

Where applicable, Case Management will review requests for the high frequency chest wall oscillation vest. Patients covered by contracts which do not have Case Management will be referred to the appropriate precertification or medical review department.

When benefits are provided for durable medical equipment, benefits **are provided** for the high frequency chest wall oscillation vest when the above criteria for medical necessity are met.

Provider Guidelines

Advanced Respiratory of St. Paul, Minnesota is the provider of The Vest®, formerly known as the ThAirapy Vest. The vest is supplied under a "lifetime lease program". Full payment of the lease term allows the patient the use of the device for life, and the device is provided with a lifetime warranty which allows for necessary repairs and replacement of all parts and accessories, including labor costs.

Cross References to Related Policies and Procedures

There are no Related Policies for this Medical Policy.

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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