MASSACHUSETTS

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Medical Policy

Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

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Policy Number: 120

BCBSA Reference Number: 1.01.15 (For Plan internal use only)

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Oscillatory Positive Expiratory Pressure Device

Use of an oscillatory positive expiratory pressure device may be considered **MEDICALLY NECESSARY** in individuals with hypersecretory lung disease (ie, produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.

High Frequency Chest Compression Device[1]

Initial use of a high frequency chest compression device is considered **MEDICALLY NECESSARY** when **ALL** of the following are met:

- The device is cleared by the U.S. Food and Drug Administration; **and**
- There is documented need for airway clearance; **and**
- The individual has **one** of the following diagnoses:
  - Cystic fibrosis; **or**
  - Chronic bronchiectasis; **or**
  - Chronic neuromuscular disorder affecting the ability to cough or clear respiratory secretions with prior history of pneumonia or other significant worsening of pulmonary function; **and**
- There is documentation of i) failure of **or** ii) inability to use other airway clearance therapies including manual chest physical therapy due to **one or more** of the following:
  - There are 2 or more individuals with cystic fibrosis, chronic bronchiectasis, or chronic neuromuscular disorder (meeting criteria above) in the family; **or**
  - The caregiver is unable (physically or mentally) to perform chest physical therapy at the required frequency; **or**
  - There is no available parental or partner resource to perform chest physical therapy; **and**
- There is documentation of an initial trial during which the affected individual and the family (when

applicable) have demonstrated compliance with the high frequency chest compression device (see the following statement for details).

Continued use of a high frequency chest compression device is considered **MEDICALLY NECESSARY** when ongoing use, (that is, compliance with use) is documented at 6 month to 12 month intervals. (Note: For high frequency chest compression devices with usage meters, documentation should reflect use, in general, at least 67% of the prescribed time.)

High frequency chest compression devices are considered **NOT MEDICALLY NECESSARY** when:

- The above criteria have not been met; **or**
- Contraindications exist for external manipulation of the thorax, as outlined by the American Association of Respiratory Care and contained in their clinical practice guidelines for Postural Drainage Therapy, which include, but may not be limited to: unstable head or neck injury; active hemorrhage with hemodynamic instability; subcutaneous emphysema; recent epidural, spinal fusion or spinal anesthesia; recent skin grafts or flaps on the thorax; burns, open wounds, and skin infections of the thorax; recently placed transvenous pacemaker or subcutaneous pacemaker; suspected pulmonary tuberculosis; lung contusion; bronchospasm; osteomyelitis of the ribs; osteoporosis; coagulopathy; and complaint of significant chest wall pain.

High frequency chest compression device replacement or upgrade is considered **NOT MEDICALLY NECESSARY** when requested for convenience or to upgrade to newer technology when the current components remain functional.

All other indications for high frequency chest compression are considered **NOT MEDICALLY NECESSARY**, including, but not limited to, chronic obstructive pulmonary disease.

Intrapulmonary Percussive Ventilation Device

Intrapulmonary percussive ventilation devices may be considered **MEDICALLY NECESSARY** in individuals with cystic fibrosis or *chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography scan) when standard chest physical therapy has failed or standard chest physical therapy is unavailable or not tolerated. In considering the chest wall compression and intrapulmonary percussive ventilation devices, there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments (ie, the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment [chest physical therapy and, if appropriate, use of an oscillatory positive expiratory pressure device] or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.)

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

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use in individuals with cystic fibrosis, chronic diffuse bronchiectasis or respiratory conditions associated with neuromuscular disorders other than as specified above, their use as an adjunct to chest physical therapy, and their use in chronic obstructive pulmonary disease are considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E0481	Intrapulmonary percussive ventilation system and related accessories
S8185	Flutter device

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
A15.0	Tuberculosis of lung
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis, unspecified
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle atrophy

G12.29	Other motor neuron disease
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G35	Multiple sclerosis
G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G70.89	Other specified myoneural disorders
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.031	Autosomal dominant limb girdle muscular dystrophy
G71.032	Autosomal recessive limb girdle muscular dystrophy due to calpain-3 dysfunction
G71.033	Limb girdle muscular dystrophy due to dysferlin dysfunction
G71.0340	Limb girdle muscular dystrophy due to sarcoglycan dysfunction, unspecified
G71.0341	Limb girdle muscular dystrophy due to alpha sarcoglycan dysfunction
G71.0342	Limb girdle muscular dystrophy due to beta sarcoglycan dysfunction
G71.0349	Limb girdle muscular dystrophy due to other sarcoglycan dysfunction
G71.035	Limb girdle muscular dystrophy due to anoctamin-5 dysfunction
G71.038	Other limb girdle muscular dystrophy
G71.039	Limb girdle muscular dystrophy, unspecified
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G71.12	Myotonia congenita
G71.13	Myotonic chondrodystrophy
G71.19	Other specified myotonic disorders
G71.2	Congenital myopathies
G71.3	Mitochondrial myopathy, not elsewhere classified
G71.8	Other primary disorders of muscles
G71.9	Primary disorder of muscle, unspecified
G72.89	Other specified myopathies
G73.7	Myopathy in diseases classified elsewhere
J39.8	Other specified diseases of upper respiratory tract
J39.9	Disease of upper respiratory tract, unspecified
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
Q33.4	Congenital bronchiectasis

Description

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require the active participation of patients. They 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 handheld 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, the vibration of the airways occurs, resulting in loosening of mucus. The Acapella device is similar in concept but uses a counterweighted plug and magnet to create air flow oscillation.

Other airway clearance techniques also require active patient participation. For example, autogenic drainage and an active cycle breathing technique both involve a combination of breathing exercises performed by the patient. Positive expiratory pressure therapy requires patients to exhale through a

resistor to produce positive expiratory pressures during a prolonged period of exhalation. It is hypothesized that the positive pressure supports the small airway such that the expiratory airflow can better mobilize secretions.

High-frequency chest wall oscillation devices (eg, the Vest Airway Clearance System) are passive oscillatory devices designed to provide airway clearance without active patient participation. 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 inflate and deflate the vest against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

All of these techniques may be alternatives to daily percussion and postural drainage in patients with cystic fibrosis, also known as chest physical therapy. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, often a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles. Oscillatory devices can also potentially be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

This evidence review addresses the outpatient use of oscillatory devices. This review does not address inpatient device use (eg, in the immediate postsurgical period).

Summary

Description

Oscillatory devices are alternatives to the standard daily percussion and postural drainage method of airway clearance for patients with cystic fibrosis. 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. Respiratory therapists and other providers may also use oscillatory devices for other respiratory conditions such as diffuse bronchiectasis, chronic obstructive pulmonary disease (COPD), and respiratory conditions associated with neuromuscular disorders.

Summary of Evidence

For individuals who have cystic fibrosis who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. The RCTs reported mixed findings and limitations such as small sample sizes and large dropout rates. A systematic review identified 39 RCTs comparing oscillatory devices with other recognized airway clearance techniques; some were published only as abstracts. Reviewers could not pool findings due to heterogeneity in study designs and outcome measures and concluded that additional adequately powered RCTs with long-term follow-up would be needed to make conclusions about oscillatory devices for cystic fibrosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have bronchiectasis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 reported the clinically important outcomes of exacerbations or hospitalizations. Only 3 RCTs reported on quality of life, and findings were mixed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic obstructive pulmonary disease (COPD) who receive oscillatory devices, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tend to have small sample sizes, short follow-up periods, and limitations in their analyses (eg, lack of intention-to-treat analysis and between-group comparisons). Moreover, the published studies reported mixed findings and did not consistently support the use of oscillatory devices

in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have respiratory conditions related to neuromuscular disorders who receive oscillatory devices, the evidence includes 2 RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. One of the RCTs was not powered to detect statistically significant differences. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvements after high-frequency chest wall compression devices versus usual care in primary outcomes, in pulmonary function measures, or in most secondary outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
8/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2022	Clarified coding information.
8/2022	Annual policy review. References added. Minor editorial refinements made to policy statements; intent unchanged.
8/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
12/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2020	Policy criteria on high frequency chest compression device revised based on expert opinion. New medically necessary indications added for chronic neuromuscular disorder. Clarified coding information. Effective 9/1/2020.
8/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Clarified coding changes.
8/2018	Annual policy review. Policy statements clarified.
1/2018	Clarified coding information.
11/2017	Annual policy review. Not medically necessary statement removed and “patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above” added to the investigational statement. Effective 11/1/2017.
11/2016	Annual policy review. Individuals with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, “disorders” changed to “conditions.” Clarified coding information. Effective 11/1/2016.
9/2015	Clarified coding information.
3/2015	Annual policy review. New references added
7/2014	Changes to medically necessary statement. Effective 7/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
5/2014	Annual policy review. New references added
3/2014	Coding information clarified.
1/2014	Updated to add new CPT code 94669.
4/2013	Annual policy review. New references added
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.

11/2010	BCBS Association National Policy Review. Changes to policy statement effective 11/2010.
3/2010	Reviewed - Medical Policy Group - Pulmonology, Allergy/Asthma/Immunology, ENT and Otolaryngology. No changes to policy statements.
9/2009	Medical policy describing covered and non-covered indications. Effective 9/1/2009.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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Endnotes

[1] Based on expert opinion A