MEDICAL POLICY

POLICY TITLE	AIRWAY CLEARANCE DEVICES
POLICY NUMBER	MP 6.015

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

I. POLICY

Mechanical Percussors

Mechanical percussors may be considered **medically necessary** for mobilizing secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist and no one competent to administer manual therapy is available.

High-Frequency Chest Compression Systems

Use of high-frequency chest compression systems, or intrapulmonary percussive ventilation (IPV) devices, may be considered **medically necessary** and appropriate for individuals with a diagnosis of one of the following:

- Cystic Fibrosis
- Chronic diffuse bronchiectasis (For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least six continuous months, or more than two times per year exacerbations requiring antibiotic therapy and confirmed by high-resolution or spiral chest CT scan)
- Neuromuscular disease with associated respiratory weakness

All the following conditions must be met:

- There is demonstrated need for airway clearance; **AND,**
- Standard chest physical therapy is unavailable or not tolerated, and there is documented clinical evidence of poor or failed outcomes using conventional chest physical therapy. (i.e., the individual has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment of chest physical therapy and, if appropriate, use of an oscillatory PEP device); **AND,**
- There is individual/family compliance with the device as evidenced by an initial trial period; **AND**

- The use of the device is consistent with U.S. Food and Drug Administration (FDA) approval.

Continued use of High Frequency Chest Compression System

Continued coverage of a high frequency chest compression system device after the 30-day trial may be considered **medically necessary** when the effectiveness of the device has been demonstrated by **BOTH** of the following:

- Documentation that the device has been used daily or as prescribed
- Documentation of increased expectoration of mucus

Note: At the end of a 30-day trial period, review of documentation regarding compliance with prescribed therapy and stable or improved respiratory status must be present. If it is determined that continued therapy is medically necessary, device rental may be continued for a total of 10 months, at which time it may be purchased.

Oscillating positive expiratory pressure (PEP) devices

Use of an oscillatory PEP device (e.g., the Flutter device, Acapella device and the Positive Expiratory Pressure (PEP) mask), may be considered **medically necessary** for patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use in patients with cystic fibrosis, or chronic diffuse bronchiectasis other than as specified above, their use as an adjunct to chest physical therapy, in other lung diseases such as chronic obstructive pulmonary disease are considered **investigational,** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for these conditions.

POLICY GUIDELINES

A trial period may be helpful because members' responses to different types of devices can vary; the types of devices should be considered as alternative, not equivalent, devices.

This policy addresses outpatient use of oscillatory devices only. Inpatient device use, e.g., in the immediate postsurgical period, is not included in the policy.

Cross-reference:

MP 6.022 Mechanical Insufflation-Exsufflation Device
MP 6.026 Durable Medical Equipment (DME) and Supplies

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

Oscillatory devices are used as 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..

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extra-thoracic. Some devices require the active participation of patients. 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 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, 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 require active patient participation. For example, autogenic drainage and active cycle of 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 (e.g., 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 can be used as alternatives to daily percussion and postural drainage, also known as chest physical therapy or chest physiotherapy, in patients with cystic fibrosis. Daily percussion and postural drainage need to be administered by a physical therapist or another trained adult in the home, typically a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who wish to 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.

Mechanical percussors are electrical devices used in place of manual chest percussion to assist with mobilizing and clearing respiratory secretions. The use of these devices involves appropriate patient or operator training by a physician or therapist. According to the guidelines developed by American Association for Respiratory Care (AARC) on postural drainage therapy, no convincing evidence demonstrates the superiority of one method over the other; however, use of a mechanical percussor can benefit the patient by allowing for independence and greater compliance.

REGULATORY STATUS

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, including those listed in Table 1.

Table 1. Select Oscillatory Devices Cleared by the Food and Drug Administration

Device	Manufacturer	Clearance Date
Flutter® Mucus Clearance Device	Axcan Scandipharm (for marketing in the United States)	1994
Vestä Airway Clearance System	Hill-Rom	1998
Acapella device	DHD Healthcare	1999
RC Cornet Mucus Clearing Device	PARI Respiratory Equipment	1999
inCourage® System	RespirTech	2005
Lung Flute®	Medical Acoustics LLC	2006
Smartvest Airway Clearance System	Electromed	2013
AerobiKA® oscillating PEP device	Trudell Medical	2013
Vibralung® Acoustical Percussor	Westmed	2014
The Vest Airway Clearance System	Hill-Rom	2015
iPEP® system including PocketPEP® and vPEP®	D R Burton Healthcare	2016

The Monarch™ Airway Clearance System	Hill-Rom	2017
Pulsehaler™	Respinova	2021

PEP: positive expiratory pressure.
U.S. Food and Drug Administration product codes: BYI, BYT

IV. RATIONALE

TOP

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 another 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 seven small RCTs on several types of oscillatory devices; only one 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 (e.g., lack of intention-to-treat analysis and between-group comparisons). Moreover, the published studies reported mixed findings and did not clearly 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.

Clinical input obtained supports the use of oscillatory devices to treat patients with cystic fibrosis and bronchiectasis, in certain situations. The most commonly mentioned clinical criteria were patients who failed or were intolerant of other methods of mucus clearance and patients who lacked caregivers to provide chest physical therapy. Thus, these devices may be considered medically necessary when chest physical therapy has failed, is unavailable, or is not tolerated by the patient.

V. DEFINITIONS

TOP

CHEST PHYSICAL THERAPY refers to a specific type of respiratory therapy that includes manual chest percussion and postural drainage.

510 (K) A premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

OSCILLATION is a swinging, pendulum-like movement.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
A7025	A7026	E0480	E0481	E0483	E0484	S8185		

ICD-10-CM Diagnosis Codes	Description
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
J41.0	Simple chronic bronchitis
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.89	Other specified chronic obstructive pulmonary disease
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
Q33.4	Congenital bronchiectasis

IX. REFERENCES

TOP

1. *Morrison L, Agnew J. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2014;7:CD006842. PMID 25038719*

2. *McIlwaine MP, Alarie N, Davidson GF, et al. Long-term multicentre randomised controlled study of high frequency chest wall oscillation versus positive expiratory pressure mask in cystic fibrosis. Thorax. Aug 2013;68(8):746-751. PMID 23407019*

3. *Sontag MK, Quittner AL, Modi AC, et al. Lessons learned from a randomized trial of airway secretion clearance techniques in cystic fibrosis. Pediatr Pulmonol. Mar 2010;45(3):291-300. PMID 20146387*
4. *Pryor JA, Tannenbaum E, Scott SF, et al. Beyond postural drainage and percussion: Airway clearance in people with cystic fibrosis. J Cyst Fibros. May 2010;9(3):187-192. PMID 20153269*
5. *Radtke T, Boni L, Bohnacker P, et al. Acute effects of combined exercise and oscillatory positive expiratory pressure therapy on sputum properties and lung diffusing capacity in cystic fibrosis: a randomized, controlled, crossover trial. BMC Pulm Med. Jun 14, 2018; 18(1): 99. PMID 29898704*
6. *Lee AL, Burge AT, Holland AE. Airway clearance techniques for bronchiectasis. Cochrane Database Syst Rev. Nov 23, 2015;11(11):CD008351. PMID 26591003*
7. *Murray MP, Pentland JL, Hill AT. A randomised crossover trial of chest physiotherapy in non-cystic fibrosis bronchiectasis. Eur Respir J. Nov 2009;34(5):1086-1092. PMID 19541717*
8. *Herrero-Cortina B, Vilaro J, Marti D, et al. Short-term effects of three slow expiratory airway clearance techniques in patients with bronchiectasis: a randomised crossover trial. Physiotherapy. Dec 2016; 102(4):357-364. PMID 26712530*
9. *Livnat G, Yaari N, Stein N, et al. 4-week daily airway clearance using oscillating positive-end expiratory pressure versus autogenic drainage in bronchiectasis patients: a randomised controlled trial. ERJ Open Res. Oct 2021; 7(4). PMID 34760994*
10. *Ides K, Vissers D, De Backer L, et al. Airway clearance in COPD: need for a breath of fresh air? A systematic review. COPD. Jun 2011; 8(3):196-205. PMID 21513439*
11. *Osadnik CR, McDonald CF, Jones AP, et al. Airway clearance techniques for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. Mar 14, 2012;3(3):CD008328. PMID 22419331*
12. *Alghamdi SM, Barker RE, Alsulayyim ASS, et al. Use of oscillatory positive expiratory pressure (OPEP) devices to augment sputum clearance in COPD: a systematic review and meta-analysis. Thorax. Oct 2020; 75(10): 855-863. PMID 32788259*
13. *Alghamdi SM, Alsulayyim AS, Alasmari AM, et al. Oscillatory positive expiratory pressure therapy in COPD (O-COPD): a randomised controlled trial. Thorax. Feb 2023; 78(2): 136-143. PMID 35948418*
14. *Chakravorty I, Chahal K, Austin G. A pilot study of the impact of high-frequency chest wall oscillation in chronic obstructive pulmonary disease patients with mucus hypersecretion. Int J Chron Obstruct Pulmon Dis. 2011; 6:693-699. PMID 22259246*
15. *Svenningsen S, Paulin GA, Sheikh K, et al. Oscillating positive expiratory pressure therapy in chronic obstructive pulmonary disease and bronchiectasis. COPD. Feb 2016; 13(1):66-74. PMID 26430763*
16. *Goktalay T, Akdemir SE, Alpaydin AO, et al. Does high-frequency chest wall oscillation therapy have any impact on the infective exacerbations of chronic obstructive pulmonary disease? A randomized controlled single-blind study. Clin Rehabil. Aug 2013; 27(8):710-718. PMID 23503735*

17. *Winfield NR, Barker NJ, Turner ER, et al. Non-pharmaceutical management of respiratory morbidity in children with severe global developmental delay. Cochrane Database Syst Rev. Oct 19, 2014; 10(10):CD010382. PMID 25326792*
18. *Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. J Child Neurol. Jul 2010; 25(7):815-821. PMID 20357238*
19. *Lange DJ, Lechtzin N, Davey C, et al. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. Neurology. Sep 26, 2006; 67(6):991-997. PMID 17000967*
20. *McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. Chest. Jan 2006; 129(1 Suppl):250S-259S. PMID 16428718*
21. *Hill AT, Barker AF, Bolser DC, et al. Treating Cough Due to Non-CF and CF Bronchiectasis With Nonpharmacological Airway Clearance: CHEST Expert Panel Report. Chest. Apr 2018; 153(4): 986-993. PMID 29355548*
22. *Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: • Simon, R. Cystic fibrosis: Overview of the treatment of lung disease. In: airway clearance therapies. Respir Care. Apr 2009; 54(4):522-537. PMID 193271*
23. *UpToDate Online Journal [serial online]. Simon, R: Cystic fibrosis: Overview of the treatment of lung disease UpToDate; updated October 2023*
24. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.15, Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions. July 2023*

X. POLICY HISTORY

TOP

MP 6.015	**CAC 8/28/12 Consensus review**. No changes to policy statements; references updated. FEP variation was revised.
	Codes reviewed 8/10/12.
	CAC 9/30/13 Consensus review References updated but no changes to the policy statements.
	CAC 5/20/14 Consensus. Adopting BCBSA policy statements while maintaining coverage for use of High-Frequency Chest Compression Systems in neuromuscular disease. Slight change in wording did not change intent of policy criteria. Codes reviewed
	CAC 6/2/15 Consensus review. Reference and rationale updated. No changes to the policy statements.
	11/2/15 Administrative change. LCD number changed from L12870 to L33785 due to NHIC update to ICD-10.
	CAC 5/31/16 Consensus review. No change to policy statements. References and rationale updated. Changed DME Medicare carrier from NHIC to Noridian. Coding reviewed**.**
	Admin update 1/1/17: Product variation section updated.

	CAC 9/27/16 Minor review. Removed minimum age 2 limitation. Added statement indicating the use of a device is to be consistent with U.S. Food and Drug Administration (FDA) approval. Added information addressing trial period and continued use. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	CAC 1/30/18 Minor revision. The not medically necessary statement for high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices was removed, Indications that were previously in this statement for use in patients with cystic fibrosis, or chronic diffuse bronchiectasis, and use in patients with respiratory conditions association with neuromuscular disorders were added to the existing investigational statement. Background, rationale, and references updated. Coding reviewed and changes recommended.
	1/1/19 Admin update: Updated E0483 with new description effective 1/1/19
	1/17/19 Consensus review. No change to the policy statements. Background table of FDA-approved devices updated. References reviewed. Rationale revised.
	1/29/2020 Consensus review. No changes made to policy statement. References updated. Coding reviewed.
	1/7/2021 Consensus Review. No change to policy statement. References reviewed and updated and coding review.
	9/22/2022 Consensus Review. Formatting changes to criteria but No change to policy statement intent. ICD 10 E84.9 added. References, policy guidelines and rationale updated.
	9/15/2023 Administrative update, Added ICD-10 code J44.89 effective 10/1/23**.**
	11/2/2023 Consensus review. Policy criteria reformatted, however no change to policy statement. Policy Guidelines, Background, Rationale and Definitions updated. References added.

Top