BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.15 Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Conditions

Effective Policy Date: October 1, 2022

Original Policy Date: December 2011

Related Policies:

None

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

Description

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.

OBJECTIVE

The objective of this evidence review is to determine whether oscillatory devices improve the net health outcome in patients with cystic fibrosis and other respiratory disorders.

POLICY STATEMENT

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 wall compression devices and intrapulmonary percussive ventilation devices may be considered **medically necessary** in individuals with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (see Policy Guidelines section) (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).

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 or chronic diffuse bronchiectasis other than as specified above, their use as an adjunct to chest physical therapy, and their use in other lung diseases such as chronic obstructive pulmonary disease or respiratory conditions associated with neuromuscular disorders, are considered **investigational**.

POLICY GUIDELINES

For this policy, chronic diffuse bronchiectasis is defined by a 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.

For the chest wall compression devices, a trial period to determine individual and family compliance may be considered. Those who appear to benefit most from the compression devices are adolescents and adults for whom, due to lifestyle factors, manual percussion and postural drainage may not be available.

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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
Vest 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.

RATIONALE

Summary of Evidence

For individuals who have cystic fibrosis (CF) who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life (QOL), 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 CF. 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, QOL, 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 QOL, 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, QOL, 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 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, QOL, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

In 2006, the guidelines from the American College of Chest Physicians recommended (level of evidence: low) that, in patients with cystic fibrosis, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physical therapy.[19,]

A 2018 document from the American College of Chest Physicians recommends that airway clearance strategies in children and adults with productive cough due to bronchiectasis related to any cause be individualized to the patient (ungraded, consensus statement).[20,]

Cystic Fibrosis Foundation

In 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence.[21,] The Foundation recommended airway clearance therapies for all patients with cystic fibrosis but stated that no therapy had been demonstrated to be superior to others (level of evidence: fair; net benefit: moderate; grade of recommendation: B).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Morrison L, Milroy S. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. Apr 30 2020; 4: CD006842. PMID 32352564
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): 746-51. 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): 187-92. 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): 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): 1086-92. 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, Vissers D, 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): 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. 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: 693-9. PMID 22259246
14. Svenningsen S, Paulin GA, Sheikh K, et al. Oscillatory Positive Expiratory Pressure in Chronic Obstructive Pulmonary Disease. COPD. 2016; 13(1): 66-74. PMID 26430763
15. 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): 710-8. PMID 23503735
16. 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): CD010382. PMID 25326792
17. 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): 815-21. PMID 20357238
18. 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): 991-7. PMID 17000967
19. McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. Chest. Jan 2006; 129(1 Suppl): 250S-259S. PMID 16428718
20. 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
21. Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respir Care. Apr 2009; 54(4): 522-37. PMID 19327189

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Policy updated with literature review. References 12, 13 and 14 added; other references renumbered or removed. No change in policy statement.
June 2014	Replace policy	Policy updated with literature review. In first 2 medically necessary statements, Flutter or Flutter and Acapella changed to oscillatory positive expiratory pressure device. References 2, 7, 8, 9, and 13 added; other references renumbered or removed. In second policy statement, "standard chest physiotherapy treatment" changed to "standard treatment€ .
June 2015	Replace policy	Policy updated with literature review. Reference 1 added. Policy statements unchanged.
September 2016	Replace policy	Policy updated with literature review through April 25, 2016; references 5, 12, and 14-16 added. Patients with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, "disorders€ changed to "conditions€ .
September 2018	Replace policy	Policy updated with literature review through April 9, 2018; reference 9 added. 'Not medically necessary" statement removed and "patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above€ added to the investigational statement
September 2019	Replace policy	Policy updated with literature review through April 1, 2019; reference added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through August 13, 2020; no references were added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 19, 2021; references added. Policy statements unchanged
September 2022	Replace policy	Policy updated with literature review through April 18, 2022; references added. Minor editorial refinements made to policy statements; intent unchanged.