

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

Effective: September 1, 2019

Next Review: June 2020

Last Review: August 2019

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for patients with cystic fibrosis, diffuse bronchiectasis and other respiratory conditions (such as chronic obstructive pulmonary disease).

MEDICAL POLICY CRITERIA

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

- I. Use of oscillatory positive expiratory pressure (OPEP) devices may be considered **medically necessary**.
- II. Use of high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices may be considered **medically necessary** when either of the following criteria are met:
 - A. For patients with cystic fibrosis when all of following criteria (1-2) are met:

1. Demonstrated need for airway clearance, and
 2. Documentation of the reason standard chest physiotherapy has failed, is not tolerated, or is unavailable or cannot be performed (e.g., caregiver inability). Failure is defined as continued frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (e.g., chest physiotherapy and, if appropriate, use of a positive expiratory pressure device).
- B. For patients with chronic diffuse bronchiectasis when all of the following criteria (1-3) are met:
1. Demonstrated need for airway clearance; and
 2. Documentation of the reason standard chest physiotherapy has failed, is not tolerated, or is unavailable or cannot be performed (e.g., caregiver inability). Failure is defined as continued frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (e.g., chest physiotherapy and, if appropriate, use of a positive expiratory pressure device).
 3. Chronic diffuse bronchiectasis must be documented by high resolution or spiral chest computed tomography scan *and* any one or more of the following must be present:
 - a. Daily productive cough for at least six continuous months; or
 - b. Exacerbations requiring antibiotic therapy three or more times per year.
- III. Use of high-frequency chest wall oscillation (HFCWO) devices and intrapulmonary percussive ventilation (IPV) devices is considered **not medically necessary** as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis in any other clinical situations.
- IV. Other applications of high-frequency chest wall oscillation devices and intrapulmonary percussive ventilation (IPV) devices are considered **investigational**, including but not limited to the following:
- A. Use as an adjunct to chest physical therapy
 - B. Use in other lung diseases, such as chronic obstructive pulmonary disease or respiratory conditions associated with neuromuscular disorders

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of specific device being requested
- Documentation of disease process including disease name (e.g. hypersecretory lung disease, cystic fibrosis, chronic diffuse bronchiectasis)

- For high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) include the following:
 - Documentation of need for airway clearance
 - Documentation of why standard chest physiotherapy has failed including reasons, if not tolerated, or is unavailable/cannot be performed including reasons.
 - If patient has chronic diffuse bronchiectasis include documentation by high resolution or spiral chest computed tomography scan along with documentation that there is a daily productive cough that has been present for six continuous months or exacerbations requiring antibiotic therapy three or more times per year.
 - Documentation if the request is going to be an adjunct to chest clinical therapy

CROSS REFERENCES

None

BACKGROUND

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require active participation of patients. They include oscillating positive expiratory pressure (PEP, or OPEP) 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 also 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. PEP therapy requires patients to exhale through a resistor to produce PEPs 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.

In contrast, high-frequency chest wall oscillation (HFCWO) devices (e.g., the Vest Airway Clearance System, formerly the ABI Vest, or the ThAIRapy Bronchial Drainage System) are oscillatory devices designed to provide airway clearance without the active participation of the patient. 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 HFCWO and mobilization of pulmonary secretions.

The Percussionaire oscillatory device delivers intrapulmonary percussive ventilation. This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

All of these techniques can be used as alternatives to daily percussion and postural drainage, also known as chest physical therapy, 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 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. In addition, they could benefit patients with neuromuscular disease who have impaired cough clearance.

REGULATORY STATUS

The following are examples of high frequency chest wall oscillation (HFCWO), and intrapulmonary percussive ventilation (IPV) devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510K approval process. FDA product codes: BYI, BYT.

Table 1. Examples of high frequency chest wall oscillation (HFCWO) and intrapulmonary percussive ventilation (IPV) devices. This list may not encompass all HFCWO and IPV devices.

Device	Device Type	Manufacturer	FDA number
ABI® Vest System	high frequency chest wall oscillation (HFCWO)	American Biosystems, Inc.	K993629
AffloVest	HFCWO	International Biophysics Corporation	K122480
Bird IPV®	Intrapulmonary percussive ventilation (IPV)	Percussionaire Corp.	K895485
Monarch® Airway Clearance System	HFCWO	Hill-Rom	K163378
SmartVest® SQL® System	HFCWO	Electromed, Inc.	K132794
SmartVest SV2100 System	HFCWO	Electromed, Inc.	K053248
ThAIRaphy®	HFCWO	American Biosystems, Inc.	K965192
Vest® Airway Clearance System	HFCWO	Hill-Rom	K142482, K024309

The following are examples of OPEP devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510K approval process. FDA product codes: BYI, BYT.

Table 2. Non-exhaustive list of oscillatory positive expiratory pressure (OPEP) devices which are not reviewed by this policy.

Device	Manufacturer	FDA number
Acapella®	Smiths Medical, Inc.	K002768
Aerobika Oscillating Positive Expiratory Pressure (OPEP)	Trudell Medical	K123400
Aerobika OPEP with Manometer	Trudell Medical	K150173
Aerosure Medic	Actegy Ltd.	K140772

Device	Manufacturer	FDA number
Flutter® Mucus Clearance Device	Axcan Scandipharm, Inc.	K946083, K940986, K972859
Lung Flute®	Medical Acoustics LLC	K091557
MetaNeb® 4 System	Hill-Rom	K151689
RC-Cornet™	PARI Respiratory Equipment	K983308
Roadrunner	DHD Healthcare	K991561
PARI PEP	PARI Respiratory Equipment, Inc.	K972042
PARI PEP S Positive Expiratory Pressure Device	PARI Respiratory Equipment, Inc.	K090829
TheraPEP®	Smiths Medical, Inc.	K944900, K962749, K983467
Vibralung Acoustical Percussor	Westmed Inc.	K133057
VibraPEP™	Curaplex	K153441

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of any oscillatory device requires randomized comparisons with standard airway clearance techniques (e.g., percussion and postural drainage). These comparisons are necessary to determine whether the benefits of oscillatory devices outweigh any risks and whether they offer advantages over conventional methods with respect to increasing quality of life and decreasing long-term morbidity and mortality, or secondary outcomes such as improved mucus clearance, lung function or rate of respiratory exacerbations.

CYSTIC FIBROSIS

Systematic Review

A 2014 updated Cochrane review evaluated oscillating devices for the treatment of cystic fibrosis.^[1,2] Investigators searched the literature for randomized controlled trials (RCTs) comparing oscillatory devices to another recognized airway clearance technique. A total of 35 RCTs with 1,050 patients met inclusion criteria. Fifteen studies used a parallel design and 20 were crossover studies. The majority (16 studies) were conducted in the United States. Sample sizes of individual studies ranged from 5 to 166, and half the studies included children. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and quality of life measures. Due to the variety of devices used, outcome measures and lengths of follow-up, a quantitative meta-analysis of multiple studies could not be performed. The authors concluded that there was a lack of evidence supporting any one airway clearance technique or device over another, and that adequately powered RCTs with long-term follow-up were needed.

Randomized Controlled Trials

Overall, RCTs have not found clear advantages of one oscillatory device over another.^[3,4] Details on studies with a minimum of one year follow-up are as follows:

Mcllwaine (2013) published an RCT comparing two types of oscillatory devices.^[5] This study differed from previous trials, because it had a larger sample size (n=107) and the primary outcome measure was a clinically meaningful outcome, i.e., the number of pulmonary exacerbations requiring an antibiotic. In addition, the study was conducted over a relatively long time period (one year), was a multicenter trial, and was not industry-funded, although industry did donate devices. The study included individuals over six years of age with clinically stable cystic fibrosis; age ranged from 6 to 47 years. Patients were randomized to perform either positive expiratory pressure (PEP) using a face mask (n=51) or high frequency chest wall oscillation (HFCWO) using the inCourage system (n=56) for one year. After randomization, there was a two-month washout period (without knowledge of treatment group assignment). Eight patients in each arm dropped out after randomization and before treatment, and another three patients dropped out during the intervention phase. A total of 88 of 107 (82%) randomized patients completed the study. By the end of one year, there were 49 exacerbations requiring antibiotics in the PEP group and 96 in the HFCWO group; the difference between groups was statistically significant, favoring PEP (p=0.007). The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group (p=0.02). There was not a statistically significant difference in pulmonary measures, including FEV1. Limitations of this study were that patients were not blinded and there was nearly a 20% drop-out rate. The trial was stopped early without enrolling the expected number of patients and, thus, may have been underpowered to detect clinically significant differences between groups.

Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis.^[6] Patients were assigned to receive treatment with P/PD (n=58), the Flutter® device (n=51), or the Vest (n=57). Investigators planned to evaluate participants on a quarterly basis for 3 years. However, dropout rates were high and consequently the trial ended early; 35 (60%), 16 (31%) and 5 (9%) patients withdrew from the postural drainage, Flutter®, and Vest groups, respectively. Fifteen patients withdrew in the first 60 days (11 of these on the day of randomization) and the remainder after 60 days. The most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13), and lack of time (n=7). At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat (ITT) analysis found no significant differences between treatment groups in the modeled rate of decline for FEV1 predicted or forced vital capacity (FVC%) predicted. The small sample size and high dropout rate greatly limit the conclusions that might be drawn from this study.

Section Summary

A number of RCTs and a systematic review (SR) have been published. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. The SR identified 35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. Study findings could not be pooled due heterogeneity in design and outcome measures. The SR concluded that additional RCTs are needed that are adequately powered and have long-term follow-up.

BRONCHIECTASIS

Systematic Reviews

Lee (2015) published a Cochrane review on airway clearance techniques for treating bronchiectasis.^[7] Seven RCTs comparing airway clearance techniques with sham or an

alternative treatment were identified.^[8-14] One hundred and five total patients were included; sample sizes ranged from 8 to 37. All studies, except one (N=37), were crossover trials. Five trials used a PEP device, one used HFCWO, and one used postural drainage. The investigators did not pool study findings due to heterogeneity among studies. Primary outcomes of interest to the Cochrane reviewers were exacerbations, hospitalizations for bronchiectasis, and quality of life (QOL). Only one trial, a crossover study with 20 patients, reported exacerbations. This trial, published by Murray (2009), did not find a statistically significant difference at 12 weeks in the number of exacerbations (there were five exacerbations with the oscillating PEP device vs seven without the oscillating PEP device; $p=0.48$).^[10] Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Three studies reported QOL outcomes. The Murray trial found significantly better health-related quality of life (HRQOL) with a PEP device compared with control, though a study by Svenningen did not. The third study, by Nicolini, used HFCWO and found significantly better HRQOL with the oscillatory device than with control.^[11] The Cochrane reviewers noted that the studies were not blinded and that patient-reported QOL measures may have been subject to bias.

Randomized Controlled Trials

RCTs evaluating HFCWO or IPV devices for bronchiectasis were not identified.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Systematic Reviews

Systematic reviews evaluating HFCWO or IPV devices for chronic obstructive pulmonary disease were not identified.

Randomized Controlled Trials

Goktalay (2013) published a study that included 50 patients with stage 3-4 COPD who were hospitalized for COPD exacerbations.^[15] Patients were randomized to receive five days of treatment with medical therapy plus HCFWO using the Vest Airway Clearance System (n=25) or medical therapy-only (n=25). At day five, outcomes, including FEV₁, scores on the MMRC dyspnea scale and the six-minute walk test, did not differ significantly between groups. This was a short-term study and included hospitalized patients who may not be similar to COPD patients treated on an outpatient basis.

Chakrovorty (2011) published a randomized cross-over study evaluating use of high-frequency chest wall oscillation in patients with moderate to severe COPD and mucus hypersecretion.^[16] Patients received HFCWO or conventional treatment, in random order, for four weeks, with a two-week wash-out period between treatments. Thirty patients enrolled in the study and 22 (73%) completed the trial; eight patients withdrew due to COPD exacerbations. The primary outcome was quality of life which was measured with the St. George's Respiratory Questionnaire (SGRQ). Only one out of four dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared to before treatment, with a decrease in the mean score from 72 to 64 ($p=0.02$). None of the four dimensions of the SGRQ improved after conventional treatment. There were no significant differences in secondary outcomes such as FEV₁ or FVC after either treatment compared to before treatment. The study was limited by small sample size, the relatively high drop-out rate, and lack of intention to treat analysis.

RESPIRATORY CONDITIONS RELATED TO NEUROMUSCULAR DISORDERS

A 2014 Cochrane review on nonpharmacologic management of respiratory morbidity in children with severe global developmental delay addressed airway clearance techniques.^[17] The review included RCTs and nonrandomized comparative studies. Three studies were identified on HFCWO (one RCT, two pre-post) and one on PEP (pre-post). Sample sizes ranged from 15 and 28 patients.

The RCT, published by Yuan (2010), compared HCFWO to standard chest physical therapy in 28 patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic.^[18] Both groups were instructed to perform the assigned treatment for 12 minutes three times a day for the study period (mean, five months). Twenty-three (82%) of 28 patients completed the study; all five dropouts were in the HCFWO group. The authors noted that the trial was exploratory and was not powered to detect statistically significant findings on of the primary outcomes (e.g., incidence and duration of acute respiratory infection requiring inpatient or patient antibiotics, adverse effects of treatment). There were no statistically significant differences between groups on primary outcomes. For example, four patients required inpatient intravenous antibiotics in the standard physical therapy group and none in the HCFWO group ($p=0.09$). In addition, seven patients required oral antibiotics in the standard physical therapy group and three in the HCFWO group ($p=NS$). No therapy-related adverse events were reported in either group. No subsequent RCTs published after their Cochrane review was identified on oscillatory devices in children with neuromuscular diseases.

In addition to the pediatric studies included in the Cochrane review, one RCT, published by Lange (2006) was identified on HFCWO in adults with amyotrophic lateral sclerosis (ALS).^[19] The trial included 46 patients with probable or definite ALS with respiratory conditions as evidenced by score on the ALS Functional Rating Scale (ALSFRS) respiratory subscale between 6 and 11 (the subscale range, 0 [complete ventilator support] to 12 [normal]). Patients were randomized to 12 weeks of HCFWO or usual care. The primary end points were measures of pulmonary function after 12 weeks. Data were available for 35 (76%) of 46 patients at 12 weeks. There were no statistically significant between-group differences in pulmonary measures (FVC predicted, capnography, oxygen saturation, or peak expiratory flow). There was also no significant difference in the ALSFRS respiratory subscale score (worsening) at 12 weeks. Of symptoms assessed as secondary outcomes, there was significantly less breathlessness and night cough in the HCFWO group than in the usual care group, and groups did not differ significantly on other symptoms, including noise of breathing, suction frequency, suction amount, day cough, and nocturnal symptoms.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF CHEST PHYSICIANS

The 2006 guidelines from the American College of Chest Physicians (ACCP) 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 physiotherapy.^[20]

CYSTIC FIBROSIS FOUNDATION

In April 2009, the Cystic Fibrosis Foundation (CFF) published guidelines on airway clearance therapies based on a SR of evidence.^[21] They recommend airway clearance therapies for all patients with cystic fibrosis but state that no therapy has been demonstrated to be superior to others (level of evidence, fair; net benefit, moderate; grade of recommendation, B). They also

issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized based on factors such as age and patient preference.

SUMMARY

OSCILLATORY POSITIVE EXPIRATORY PRESSURE (OPEP)

There is enough research to show that oscillatory positive expiratory pressure (OPEP) devices improve health outcomes. Practice guidelines based on research recommend the use of OPEP devices. Therefore, oscillatory positive expiratory pressure devices may be considered medically necessary.

HIGH-FREQUENCY CHEST WALL OSCILLATION DEVICES (HFCWO) AND INTRAPULMONARY PERCUSSIVE VENTILATION (IPV) DEVICES

There is enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices improve health outcomes for people with cystic fibrosis or chronic diffuse bronchiectasis. Therefore, HFCWO and IPV may be considered medically necessary when the policy criteria are met.

There is not enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices are a medically necessary alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis, in any other clinical situations. Therefore, HFCWO and IPV are considered not medically necessary as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis when the policy criteria are not met.

There is not enough research to show that high-frequency chest wall oscillation devices (HFCWO) and intrapulmonary percussive ventilation (IPV) devices improve health outcomes as an adjunct to chest physical therapy or for people with chronic obstructive pulmonary disease (COPD) and respiratory conditions associated with neuromuscular disorders. Therefore, the use of HFCWO and IPV devices as an adjunct to chest physical therapy or for patients with chronic obstructive pulmonary disease (COPD) and respiratory conditions associated with neuromuscular disorders is considered investigational.

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CODES

NOTES:

- Devices have codes specific to their technology, e.g., IPV is reported by E0481.
- Oscillatory positive expiratory pressure (OPEP) are reported by E0484 and S8185.

Codes	Number	Description
CPT	None	
HCPCS	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
	E0481	Intrapulmonary percussive ventilation system and related accessories
	E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

Date of Origin: May 2011