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Medical Policy Manual

Topic: Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

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Section: Durable Medical Equipment

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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; also known as chest physical therapy or chest physiotherapy) method of airway clearance for patients with cystic fibrosis, and other respiratory conditions, such as diffuse bronchiectasis and chronic obstructive pulmonary disease (COPD). P/PD needs to be administered by a 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.

There are several types of devices including high-frequency chest compression with an inflatable vest and oscillating positive expiratory pressure devices. The oscillatory component of these devices can be intra-thoracic, requiring active participation of the patient (i.e., active oscillatory devices), or extra-thoracic which does not require active participation (i.e., passive oscillatory devices).

Examples of active oscillatory devices include oscillating positive expiratory pressure (PEP) devices, such as Flutter®, Acapella®, and RC-Cornet™ in which the patient exhales multiple times through a device 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.

Examples of passive oscillatory devices include the following:

- The Vest® Airway Clearance System (formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System), which 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.
- Intrapulmonary percussive ventilation (IPV®) devices distributed by the Percussionaire® Corporation combine internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

Regulatory Status

The following are oscillatory devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510K approval process:

Active Devices

- Flutter® Mucus Clearance Device (Axcan Scandipharm, Inc.)
- The Acapella® device (DHD Healthcare)
- RC-Cornet™ Mucus Clearing Device (PARI Respiratory Equipment)

Passive Devices

- Intrapulmonary Percussive Ventilation (IPV, Bird IPV®) devices (Percussionaire Corp.)
- Vest® Airway Clearance System (this is the fifth generation of the originally approved ThAIRapy Bronchial Drainage System, Hill-Rom)
- The inCourage® System (Respiratory Technologies, Inc.)

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

MEDICAL POLICY CRITERIA

I. Use of active oscillatory devices, (e.g., the Flutter® valve, RC-Cornet™, or Acapella® devices) may be considered **medically necessary** in patients with hypersecretory lung disease (i.e., producing excessive mucus) who have difficulty clearing the secretions and have recurrent disease exacerbations.

II. Use of passive oscillatory devices, (e.g., high-frequency chest wall compression devices or intrapulmonary percussive ventilation (IVP) devices) may be considered **medically necessary** in patients with cystic fibrosis or chronic diffuse bronchiectasis as determined by specific criteria (see II.C.) when both criteria A and B are met:

   A. Demonstrated need for airway clearance, and

   B. 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 an active oscillatory device).

C. For this policy, chronic diffuse bronchiectasis must be documented by high resolution or spiral chest computed tomography scan AND one or both of the following must be present:

1. Daily productive cough for at least 6 continuous months, OR

2. Exacerbations requiring antibiotic therapy 3 or more times per year.

III. Use of passive oscillatory 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 passive oscillatory 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

SCIENTIFIC EVIDENCE

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

In 2009, a Cochrane review that evaluated the evidence on oscillating devices for the treatment of cystic fibrosis was published.[1] Investigators searched the literature through November 2008 for randomized controlled trials (RCTs) comparing oscillatory devices to another recognized airway clearance technique. A total of 30 studies with 708 patients met inclusion criteria. Eleven studies used a parallel design and 19 were crossover studies. Ten of the included studies were published as abstracts only. The majority (16 studies) were conducted in the United States. Sample sizes of individual studies ranged from 5 to 166, with a median of 20 participants. Sixteen studies used the Flutter® device as a comparison, 11 used high-frequency chest wall oscillation, 5 used intrapulmonary percussive ventilation, and 2 used the R-C Cornet™ device. No studies were identified that compared the Acapella® device to another treatment. Study duration ranged from 1 week to 1 year; 21 of the studies were of less than 3 months' duration and 10 lasted less than 1 week. 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 randomized controlled studies with long-term follow-up were needed.

Randomized Controlled Trials (RCTs)

Several additional RCTs have been published since the 2009 Cochrane review. Similar to the trials identified in the Cochrane review, these tended to be underpowered due to small sample sizes[2,3] and/or high dropout rates and did not find clear advantages of one oscillatory device over another. Details on three recent studies with longer-term follow-up are as follows:

- Pryor and colleagues evaluated patients aged 16 years and older with cystic fibrosis from a single center in the U.K.[4] The 75 patients were randomly assigned to receive 1 of 5 treatments for 1 year (15 per group): the Cornet device, the Flutter® device, PEP, active cycle of breathing technique, or autogenic drainage. Sixty-five of 75 (87%) patients completed the study, and these were included in the analysis. Mean forced expiratory volume in one second (FEV1) values at 12 months, the primary outcome, were 1.90 +/- 0.89 in the Cornet group (n=14), 2.43 +/- 0.94 in the Flutter® group (n=12), 2.02 +/- 1.17 in the PEP group (n=13), 1.94 +/- 0.80 in the active cycle of breathing group (n=13), and 2.64 +/- 1.22 in the autogenic drainage group (n=13). The difference among the 5 groups was not statistically significant for FEV1 or any other lung function variable; however, this study is unreliable due to the small number of patients per group.

- Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis.[5] 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.

- In 2013, Mcllwaine and colleagues published an RCT comparing 2 types of oscillatory devices.[6] 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 (1 year), was a multicenter trial, and was not industry-funded, although industry did donate devices.

  The study included individuals over 6 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, active device) using a face mask (n=51) or high frequency chest wall oscillation (HFCWO, passive device) using the inCourage system (n=56) for 1 year. After randomization, there was a 2 month washout period (without knowledge of treatment group assignment). Eight patients in each arm dropped out after randomization and before treatment, and another 3 patients dropped out during the intervention phase. A total of 88 of 107 (82%) randomized patients completed the study. By the end

of 1 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.

Conclusion

Overall the evidence has not demonstrated that oscillatory devices are more beneficial than chest physiotherapy as a treatment for cystic fibrosis. In addition, there is limited evidence that any one device is superior to another, although a recent RCT demonstrated better outcomes with an active device compared to a passive one.

Other Respiratory Disorders

There are fewer studies on use of oscillatory devices for treatment of respiratory diseases other than cystic fibrosis. Identified studies mainly focused on the use of these devices in patients with bronchiectasis or COPD.

Systematic Reviews

- In 2013, Lee and colleagues published a Cochrane review on airway clearance techniques for treating bronchiectasis.[7] Five small RCTs comparing airway clearance techniques to sham or an alternative treatment were identified. Sample sizes ranged from 8 to 20 patients and the 5 studies included a total of 51 patients. Three of the 5 trials used the Flutter® device and all were unblinded. The investigators did not pool study findings. Only 1 trial, a crossover study with 20 patients, reported primary outcomes of interest to Cochrane investigators; exacerbations and quality of life. This study, published by Murray and colleagues, did not find a statistically significant difference at 12 weeks in the number of exacerbations; there were 5 exacerbations with the Acapella® device and 7 without the Acapella® device (p=0.48).[8] There was significantly better cough-related quality of life after 12 weeks of airway clearance compared to no airway clearance.

- In 2011, Ides and colleagues published a systematic review of airway clearance in chronic obstructive pulmonary disorder (COPD).[9] The review identified 6 studies evaluating positive expiratory pressure (PEP) in COPD patients, alone or in combination with another airway clearance technique. Two studies used the Flutter® device and two used the Cornett device. Sample sizes in individual studies ranged from 10 to 37 patients; study findings were not pooled. The authors concluded:

  > "Evidence on the effects of airway clearance techniques such as PEP [positive expiratory pressure], oscillating PEP, PD [postural drainage] and vibration in COPD patients is poor. This is possibly due to a lack of appropriate trials rather than any evidence for lack of benefit. Clinical guidelines for use of mechanical and supporting techniques seem to be lacking."

Randomized Controlled Trials (RCTs)

- In 2013, Nicolini and colleagues reported a randomized trial of 30 patients with bronchiectasis, who were assigned to one of three groups: 10 patients treated with high-frequency airway clearance

(HFCWC) devices by using the Vest® Airway Clearance System; 10 patients treated with traditional techniques of air way clearance (PEP bottle, PEP mask, ELTGOL, vibratory positive expiratory pressure); 10 patients received medical therapy only (control group).[10] The aim of the study was to compare HFCWC devices to chest physiotherapy (CPT) as a treatment for patients with bronchiectasis. Blood tests, sputum volume and cell count, pulmonary function tests and quality of life inventories [Modified Medical Research Council (MMRC) Dyspnea Scale, COPD Assessment Test (CAT), and Breathlessness, Cough and Sputum Scale (BCSS)] were collected before and after treatment. Results showed a significant improvement in quality of life, biochemical and respiratory tests with HFCWC devices and CPT; however, this study is limited by its small sample size which limits conclusions regarding the effectiveness of HFCWC devices as a treatment for bronchiectasis.

- In 2013, Goktalay and colleagues published a study that included 50 patients with stage 3-4 COPD who were hospitalized for COPD exacerbations.[11] Patients were randomized to receive 5 days of treatment with medical therapy plus HCFWO using the Vest Airway Clearance System (n=25) or medical therapy-only (n=25). At day 5, outcomes, including FEV1, scores on the MMRC dyspnea scale and the 6-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.

- In 2011, Chakrovorty and colleagues published a randomized cross-over study evaluating use of high-frequency chest wall oscillation in patients with moderate to severe COPD and mucus hypersecretion.[12] Patients received HFCWO or conventional treatment, in random order, for 4 weeks, with a 2-week wash-out period between treatments. Thirty patients enrolled in the study and 22 (73%) completed the trial; 8 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 1 out of 4 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 4 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.

- Thompson and colleagues compared the Flutter® device with active cycle of breathing technique (breathing control, thoracic expansion exercises, and forced expiratory technique) in the home in 17 patients with non-cystic fibrosis bronchiectasis.[13] When measuring sputum weight, peak expiratory flow rate, breathlessness, bronchodilator spirometric tests, and health-related quality of life, no significant difference in outcomes was noted with use of either treatment modality. Patient preference favored the Flutter® device (11 of 17).

- In a RCT from New Zealand reporting on 18 patients with chronic bronchiectasis, Eaton et al. found an increase in dry sputum weight for active cycle of breathing technique (ACBT) with postural drainage compared with use of just ACBT or use of the Flutter® device.[14]

- The other randomized trial was a cross-over study evaluating the acapella device. In a small study of 20 patients with acute exacerbation of bronchiectasis during antibiotic therapy, Patterson et al. found no difference in changes in lung function with the "usual" airway clearance approach compared with acapella.[15]

Conclusion

The small size and discrepant findings of available literature on oscillatory devices in chronic bronchiectasis do not permit assessment of the effectiveness of these devices compared with standard medical care. In addition, there are limited studies evaluating oscillatory devices for the treatment of COPD and the available evidence did not tend to find that these devices were more effective than conventional treatment.

Clinical Practice Guidelines

Several evidence-based clinical practice guidelines have been identified which recommend the use of some types of oscillatory devices:

American College of Chest Physicians (ACCP)

The 2006 guidelines from the 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.[16]

Cystic Fibrosis Foundation (CFF)

In April 2009, the CFF published guidelines on airway clearance therapies based on a systematic review of evidence.[17] 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

Cystic Fibrosis and Diffuse Bronchiectasis

In patients with cystic fibrosis, it is difficult to reach scientific conclusions regarding the relative efficacy of oscillatory therapies compared with daily percussion and postural drainage (P/PD), considered the standard therapy for mucus clearance in patients with cystic fibrosis. Active oscillatory devices primarily represent a convenience for patient, and it is on this basis that they are considered medically necessary. In contrast, intrapulmonary percussive ventilation or high-frequency chest wall compression devices, also known as passive oscillatory devices, are more complex devices and are considered medically necessary for treatment of cystic fibrosis or diffuse bronchiectasis only when conventional chest physical therapy has failed or is unavailable. In all other situations, due to lack of evidence regarding effectiveness compared with standard medical care, the use of intrapulmonary percussive ventilation or high-frequency chest wall compression devices is considered not medically necessary.

Other Chronic Pulmonary Diseases

There is insufficient evidence regarding the impact of high-frequency chest wall compression and intrapulmonary percussive ventilation devices on health outcomes related to other chronic pulmonary diseases such as chronic obstructive pulmonary disease (COPD) or bronchiectasis; therefore, the use of these devices in these patients is considered investigational.

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CROSS REFERENCES

None

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 air-pulse generator system (includes hoses and vest), each
	E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
	S8185	FLUTTER device