APPENDIX to Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Diseases Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some of the devices require the active participation of the patient. These include oscillating positive expiratory pressure (PEP) devices, such as the FLUTTER® mucus clearance device (Axcan Scandipharm Inc., Birmingham, AL) and the Acapella® Vibratory PEP Therapy System (Smiths Medical, London, England), in which the patient exhales multiple times through a device. The FLUTTER device is a small pipe-shaped, easily portable hand-held 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 (ACBT) both involve a combination of breathing exercises performed by the patient. Positive expiratory pressure (PEP) therapy requires patients to exhale through a resistor to produce PEP 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 (HFCW) oscillation devices (e.g., the Vest Airway Clearance System, formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System) are passive oscillatory devices designed to provide airway clearance without the active participation of the patient. The Vest® Airway Clearance System (Hill-Rom Services, Inc., St. Paul, MN) 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. (See Policy Guideline for list of oscillatory devices).

Another type of passive oscillatory device, the Percussionaire IPV® (Percussionaire® Corporation, Sandpoint, ID), delivers intrapulmonary percussive ventilation (IPV). This device combines internal thoracic percussion through rapid minibursts of inhaled air and continuous therapeutic aerosol delivered through a nebulizer.

All of the above techniques can be used as alternatives to daily percussion and postural drainage (P/PD), also known as chest physical therapy or chest physiotherapy, in patients with cystic fibrosis. Percussion and postural drainage needs 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 disorder (COPD).

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.

Cystic Fibrosis

A 2009 Cochrane review evaluated the evidence for the treatment of cystic fibrosis (CF) with the use of oscillating devices (Morrison & Agnew, 2009). Investigators searched the literature through November 2008 for randomized controlled trials (RCTs) comparing oscillatory devices to other recognized airway clearance techniques. 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 studies were published as abstracts only. Sixteen were conducted in the United States. Sample sizes of individual studies ranged from 5 to 166, with a median of 20 participants. There were 16 studies using the FLUTTER device as a comparison, 11 using high-frequency chest wall oscillation, 5 using IPV, and 2 using the RC Cornet™ Mucus Clearing Device. No studies were identified comparing Acapella to another treatment. Study duration ranged from 1 week to 1 year; 21 of the studies were of less than three 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, quantitative meta-analyses of multiple studies could not be performed. The authors concluded there was a lack of evidence supporting any one airway clearance technique or device over another and there was a need for adequately powered RCT studies with long-term follow-up.

Findings from selected RCTs included in the Cochrane review are described below:

Oermann and colleagues (2001) conducted a pilot study of 24 patients with CF who were randomly assigned to receive either the Vest Airway Clearance System or the FLUTTER device for 4 weeks followed by crossover to the other group. Spirometry, lung volume measures, quality of life, and patient satisfaction were measured after each four-week treatment period. The only significant difference between the groups was patient satisfaction; 50% of the participants preferred the Vest Airway Clearance System, while 37% preferred the FLUTTER device.

App and colleagues (1998) performed a randomized trial with a crossover design comparing the Flutter device and autogenic drainage in 14 patients with cystic fibrosis. Patients received therapy with either autogenic drainage or the Flutter device and then crossed over to the alternate treatment. At the beginning and end of each 4-week interval, pulmonary function was measured before and after an acute 30-minute therapy. At the end of the session, the weight and viscoelasticity of the sputum were evaluated. No significant changes in pulmonary function or sputum volume were noted throughout the study. Sputum viscoelasticity was lower in those receiving Flutter therapy, potentially allowing it to be cleared more easily by cough and airflow mechanisms.

Newhouse and colleagues (1998) reported on the results of a randomized trial with crossover design that compared the results of the Percussionaire device and the Flutter device in 8 patients with cystic fibrosis. Each regimen was randomly administered to each patient on 3 separate days during 3 successive weeks. Post-treatment pulmonary function tests were obtained at 1 and 4 hours after each treatment regimen. The weight of sputum samples collected over 4 hours after treatment was also recorded. There was no difference in sputum quantity with any method studied. Results of pulmonary function tests were inconsistent in this small trial.

In a randomized trial, McIlwaine and colleagues (2001) compared PEP and the FLUTTER device in 40 children with CF. Participants were randomly assigned to physiotherapy with PEP or the FLUTTER device for 1 year. Clinical status, pulmonary function, and compliance were measured at regular intervals throughout the year. In the PEP group the pulmonary function remained relatively stable, while in the FLUTTER group, there was a greater mean annual rate of decline in forced vital capacity (FVC). This difference did not become apparent until 6 to 9 months into the study, underlining the importance of long-term results.

Varekojis and colleagues (2003) compared HFCW compression using the Vest and IPV using the Percussionaire® device to P/PD in 24 hospitalized patients with CF. Patients used each modality for 2 days in a randomized order over a 6-day period. While wet sputum weights from use of the Percussionaire® device were significantly greater than the Vest, there was no significant difference in any of the modalities in dry sputum weights. In addition, patients found use of each of the devices to be equally acceptable when questioned about comfort, convenience, effectiveness, and ease of use.

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 and/or high dropout rates and did not find clear advantages of one oscillatory device over another. Details on two recent studies with longer-term follow-up are as follows:

Pryor and colleagues (2010) evaluated patients aged 16 years and older with CF from a single center in the United Kingdom. Seventy-five patients were randomly assigned to receive 1 of 5 treatments for 1 year (15 per group): the Cornet device, the FLUTTER device, PEP, ACBT or autogenic drainage. Sixty-five of 75 (87%) patients completed the study, and these were included in the analysis. Mean forced expiratory volume in 1 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 had a small number of patients per group.

Sontag and colleagues (2010) conducted a multicenter randomized trial with 166 adults and children with CF. 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 P/PD, 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 FVC % predicted. The small sample size and high dropout rate greatly limit the conclusions that might be drawn from this study.

Bronchiectasis

Several small RCTs were identified that included patients with bronchiectasis. On 2002, Thompson and colleagues compared the Flutter device to the active cycle of breathing technique in 17 patients. There were no significant between-group differences in outcomes e.g., peak expiratory flow rate, spirometric tests, and quality of life. In a 2007 cross-over study with 36 patients, Eaton and colleagues compared the Flutter device, the active cycle of breathing technique and active cycle of breathing plus postural drainage, in random order. Total sputum weight was highest after active cycle of breathing plus postural drainage; patient preference was highest for use of the Flutter device. In a study of 20 patients in 2007 with acute exacerbation of bronchiectasis during antibiotic therapy, Patterson and colleagues found no difference in changes in lung function with the “usual” airway clearance approach compared to Acapella.

Chronic Obstructive Pulmonary Disease (COPD)

At least 2 systematic reviews of studies on airway clearance techniques in patients with COPD have been published (Ides et al., 2011; Osadnic et al., 2012). Both reviews addressed a variety of techniques i.e., they were not limited to studies on oscillatory devices. The 2011 review by Ides and colleagues identified 6 studies evaluating positive expiratory pressure in COPD patients, 4 of

which used oscillatory devices (Flutter or Cornet), and 1 study on high-frequency chest wall oscillation. Sample sizes in individual studies ranged from 10 to 50 patients; the study with the largest sample size was published in German. The Ides review did not pool study findings but the authors commented that the evidence on techniques such as oscillating PEP is poor due to a lack of appropriate trials. The 2012 Cochrane review on airway clearance techniques for COPD did not specifically discuss the number of studies or the results of studies on oscillatory devices (Osadnic et al., 2012).

In 2011, Chakrovorty and colleagues in the United Kingdom published a randomized cross-over study evaluating use of HFCW oscillation in patients with moderate to severe COPD and mucus hypersecretion. Patients received HFCW oscillation 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; this was measured with the St. George's Respiratory Questionnaire (SGRQ). Only 1 out of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCW oscillation 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 the relatively high drop-out rate and lack of intention-to-treat analysis.

Ongoing clinical trials

An open-label RCT, long-term study (2013) is being conducted in Canada and is sponsored by the University of British Columbia. This study is comparing the safety and efficacy of HFCW oscillation using the Vest System to PEP in the treatment of CF. The study includes patients age 6 years and older with cystic fibrosis, and estimated enrollment is 1,707 individuals. The primary outcome measure is the difference between groups in the number of respiratory exacerbations during 1 year.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

In response to requests by Blue Cross Blue Shield Association, input was received from 2 academic medical centers in December 2008. The reviewers indicated that the available studies demonstrate that these devices are comparable to chest physiotherapy for both cystic fibrosis and bronchiectasis.

Summary

Oscillatory devices are designed to move mucus and clear airways. In patients with cystic fibrosis, it is difficult to reach scientific conclusions regarding the relative efficacy of oscillatory therapies compared to standard treatment with daily percussion and postural drainage. However, findings from randomized controlled trials, combined with clinical input, suggest that oscillatory devices may be comparable to chest physical therapy for cystic fibrosis patients in some situations. The available evidence and clinical input also suggest that oscillatory devices may be appropriate for treating diffuse bronchiectasis in similar situations. Thus, these devices may be considered medically necessary when chest physical therapy has failed or is unavailable or not

tolerated by the patient. The sparse data do not suggest that any one oscillatory device is superior to another for cystic fibrosis or bronchiectasis. The Flutter® device, autogenic drainage, and PEP are simple devices or maneuvers that can be learned by most patients. In contrast, IPV or HFCW compression, (e.g., with the Vest™ Airway Clearance System) are more complex devices.

The use of HFCW compression and IPV devices in other chronic pulmonary diseases, such as COPD, is considered investigational due to insufficient evidence on the impact of treatment on health outcomes.

Practice Guidelines and Position Statements

The 2006 guidelines from the American College of Chest Physicians recommend (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 (McCool & Rosen, 2006).

In April 2009, the Cystic Fibrosis Foundation published guidelines on airway clearance therapies based on a systematic review of evidence (Flume et al., 2009). 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.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	None	

Type	Number	Description
HCPC	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
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- N/A

Key / Related Searchable Words

- Acapella Device
- Cystic Fibrosis

- Flutter Device
- High Frequency Chest Compression
- Intrapulmonary Percussive Ventilation (IVP)
- IPV (Intrapulmonary Percussive Ventilation)
- Oscillatory Devices for Cystic Fibrosis
- Percussionaire
- RC-Cornet Mucus Clearing Device
- ThAIRapy Vest
- Vest® Airway Clearance System

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
12/1/2004	Administrative Review Administrative review of external experts by Policy Committee, accepted as New Policy	Medical Policy Committee
6/1/2005	Administrative Review with statement unchanged	Administrative Review
12/7/2006	Policy Revision Indication updated - BCBSA MPP	Medical Policy Committee

Effective Date	Action	Reason
9/12/2008	Policy Review and revision. Policy title change. Prior Policy title: Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders.	Medical Policy Committee
7/1/2011	Policy revision with position change	Medical Policy Committee
9/27/2013	Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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