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

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 12/18/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider high-frequency chest wall compression devices as an alternative to chest physical therapy for airway clearance in patients with cystic fibrosis or chronic diffuse bronchiectasis (as determined by specific criteria including chest computed tomography scan) when standard chest physiotherapy has failed (i.e., the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite percussion and postural drainage) or standard chest physiotherapy is unavailable or not tolerated may be considered to be eligible for coverage.

Based on review of available data, the Company may consider the use of the FLUTTER® valve or Acapella device in patients with hypersecretory lung disease (i.e., production of excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations to be eligible for coverage.

Note: For this policy, chronic diffuse bronchiectasis is defined by daily productive cough for at least 6 continuous months or more than 2 times per year exacerbations 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 patient and family compliance may be considered. Those who appear to benefit most from the compression devices are adolescents and adults due to lifestyle factors in which manual percussion and postural drainage (P/PD) may essentially not be available.

A trial period may also be helpful because patients’ responses to the various types of devices can be variable; the types of devices should be considered as alternative, and not equivalent, devices.

When Services Are Considered Not Medically Necessary
High-frequency chest wall compression devices as an alternative to chest physical therapy in patients with cystic fibrosis or chronic bronchiectasis in any other clinical situations are considered to be not medically necessary**; there are no clinical data to show that these devices provide any additional health benefit compared to conventional chest physical therapy in these situations.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intrapulmonary percussive ventilation devices in the treatment of patients with chronic pulmonary diseases including cystic fibrosis and bronchiectasis to be investigational.*

Based on review of available data, the Company considers other applications of high-frequency chest wall compression devices, including but not limited to their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disorder, to be investigational.*

Background/Overview

Oscillatory devices are used as alternatives to the standard daily P/PD 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. Oscillatory devices are also proposed for other respiratory conditions such as diffuse bronchiectasis and chronic obstructive pulmonary disorder (COPD).

Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extra-thoracic. Some of the devices require the active participation of the patient. 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 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 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 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.

In contrast, high-frequency chest wall compression 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 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.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

The Percussionaire device delivers intrapulmonary percussive ventilation (IPV) and is another type of passive oscillatory device. 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 P/PD, also known as chest physical therapy or chest physiotherapy, in patients with cystic fibrosis. P/PD 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 COPD.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several oscillatory devices have been cleared for marketing by the U.S. FDA through the 510(k) process including the following:

- The Bird IPV® Noncontinuous Ventilator (Percussionaire Corp) in 1989.
- FLUTTER™ Mucus Clearance Device in 1994. The FLUTTER device is currently marketed in the United States by Axcan.
- The ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by the FDA—most recently a fifth generation device. The device is now known as the Vest™ Airway Clearance System, and it is manufactured by Hill-Rom.
- The Acapella® device (DHD Healthcare) in 1999.
- The RC Cornet™ Mucus Clearing Device (PARI Respiratory Equipment) in 1999.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination.

Rationale/Source

Cystic Fibrosis

In 2009, a Cochrane review was published that evaluated the evidence on oscillating devices for the treatment of cystic fibrosis. Investigators identified 30 randomized controlled trials (RCTs) with 708 patients that compared oscillatory devices to another recognized airway clearance technique. Eleven studies used a parallel design and 19 were crossover studies. Ten of the included studies were published as abstracts only. The majority, 16, 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 intrapulmonary percussive ventilation, and 2 using Cornet. No studies were identified that compared Acapella 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. Findings of the studies could not be pooled due to the variety of devices used, outcome measures and lengths of follow-up. The authors concluded that there is a lack of evidence supporting any one airway clearance technique or device over another and that there is a need for adequately powered randomized controlled studies with long-term follow-up.
Findings from selected randomized controlled trials included in the Cochrane review are described below:

Oermann and colleagues conducted a pilot study of 24 patients with cystic fibrosis 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 4-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 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 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 compared PEP and the Flutter device in 40 children with cystic fibrosis. 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. This difference did not become apparent until 6 to 9 months into the study, underlining the importance of long-term results.

Varekojis and colleagues compared high-frequency chest wall compression using the Vest and intrapulmonary percussive ventilation using the Percussionaire device to P/PD in 24 hospitalized patients with cystic fibrosis. 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 earlier trials, 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 representative recent studies are as follows:
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

Pryor and colleagues evaluated patients aged 16 years and older with cystic fibrosis from a single center in the U.K. 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 had a small number of patients per group.

Sontag and colleagues conducted a multicenter randomized trial with 166 adults and children with cystic fibrosis. 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.

Bronchiectasis

Several small RCTs were identified that included patients with bronchiectasis. 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 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 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. 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.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

Policy #  00090
Original Effective Date:  03/24/2003
Current Effective Date:  12/18/2013

In 2011, Chakrovorty and colleagues in the United Kingdom published a randomized cross-over study evaluating use of high-frequency chest wall oscillation (HFCWO) in patients with moderate to severe COPD and mucus hypersecretion. 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; 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 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 the relatively high drop-out rate and lack of intention-to-treat analysis.

Ongoing clinical trials
Long-term study, comparing Vest therapy to Positive Expiratory Pressure (PEP) therapy in the treatment of cystic fibrosis (NCT00817180): This open-label RCT is comparing the safety and efficacy of high-frequency chest wall oscillation using the Vest System to PEP. 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. The study is being conducted in Canada and is sponsored by the University of British Columbia.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 2 academic medical centers while this policy was under review in December 2008. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. 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 positive expiratory pressure are simple devices or maneuvers that can be learned by most patients. In contrast, intrapulmonary percussive ventilation or high-frequency chest wall compression, e.g., with the Vest Airway Clearance System are more complex devices.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

Policy # 000090
Original Effective Date: 03/24/2003
Current Effective Date: 12/18/2013

The use of high-frequency chest wall compression and intrapulmonary percussive ventilation devices in other chronic pulmonary diseases, such as COPD, is considered investigational due to insufficient evidence on the impact of treatment on health outcomes.

References

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

Policy #  00090
Original Effective Date: 03/24/2003
Current Effective Date: 12/18/2013

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>No code</td>
</tr>
<tr>
<td>HCPCS</td>
<td>A7025, A7026, E0481, E0483</td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td>277.00 thru 277.09, 494.0, 494.1</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>93.18</td>
</tr>
</tbody>
</table>

Policy History

Original Effective Date: 03/24/2003
Current Effective Date: 12/18/2013
12/19/2002 Medical Policy Committee review
03/24/2003 Managed Care Advisory Council approval
12/16/2003 Medical Director review
01/27/2004 Managed Care Advisory Council approval
03/08/2004 Medical Director review
03/16/2004 Medical Policy Committee review. Policy revision addresses investigation status of the use of oscillatory devices for the treatment outside of cystic fibrosis.
03/29/2004 Managed Care Advisory Council approval
03/01/2005 Medical Director review
03/15/2005 Medical Policy Committee review
04/04/2005 Managed Care Advisory Council approval
04/05/2006 Medical Director review
04/19/2006 Medical Policy Committee approval. Format Revisions: FDA/Governmental Regulations, Rationale/Source
03/14/2007 Medical Director review
03/21/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2008 Medical Director review
07/16/2008 Medical Policy Committee approval. Coverage eligibility unchanged.
07/02/2008 Medical Director review
07/22/2009 Medical Policy Committee approval. Extensively revised the coverage section.
12/01/2010 Medical Policy Committee review
12/08/2011 Medical Policy Committee review

©2013 Blue Cross and Blue Shield of Louisiana
An independent licensee of the Blue Cross and Blue Shield Association
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 12/18/2013

12/06/2012 Medical Policy Committee review
12/19/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2013 Medical Policy Committee review
12/18/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 12/2014

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.