I. POLICY

Mechanical Percussors

Mechanical percussors may be considered medically necessary for mobilizing secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist and no one competent to administer manual therapy is available.

High-Frequency Chest Compression Systems

Use of high-frequency chest compression systems, e.g., the Vest® Airway Clearance System, or intrapulmonary percussive ventilation (IPV) devices, e.g., Percussionaire, may be considered medically necessary and appropriate for individuals with a diagnosis of one of the following:

- Cystic fibrosis,
- Chronic diffuse, bronchiectasis*
- Neuromuscular disease with associated respiratory weakness

* 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 CT scan.

AND

All of the following conditions are met:

- There is demonstrated need for airway clearance, AND
- There is patient/family compliance with the device as evidenced by an initial trial period. AND
- The use of the device is consistent with U.S. Food and Drug Administration (FDA) approval.
AND ONE of the following: (see policy guidelines)

- Standard chest physical therapy is unavailable.
- Standard chest physical therapy is not tolerated
- There is documented clinical evidence of poor or failed outcomes using conventional chest physical therapy. i.e., the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physical therapy and, if appropriate, use of an oscillatory PEP device).

**Continued use of High Frequency Chest Compression System**

Continued coverage of a high frequency chest compression system device after the 30 day trial is considered medically necessary when the effectiveness of the device has been demonstrated by both of the following:

- Documentation that the device has been used daily or as prescribed
- Documentation of increased expectoration of mucus

Note: At the end of a 30 day trial period, review of documentation regarding compliance with prescribed therapy and stable or improved respiratory status must be present. If it is determined that continued therapy is medically necessary, device rental may be continued for a total of 10 months, at which time it may be purchased.

High-frequency chest wall compression devices and intrapulmonary percussive ventilation devices are considered not medically necessary as an alternative to chest physical therapy in patients with cystic fibrosis, chronic bronchiectasis or neuromuscular disease with associated respiratory weakness in any other clinical situations; there are no clinical data to show that these devices provide any additional health benefit compared with conventional chest physical therapy in situations other than those specified above.

Other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including, but not limited to, their use as an adjunct to chest physical therapy, in other lung diseases such as chronic obstructive pulmonary disease are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these conditions.

**Oscillating positive expiratory pressure (PEP) devices**

Use of an oscillatory PEP device (e.g., the Flutter device, Acapella device and the Positive Expiratory Pressure (PEP) mask), may be considered medically necessary for patients with hypersecretory lung disease (i.e., produce excessive mucus) who have difficulty clearing the secretions and recurrent disease exacerbations.
Policy Guidelines

In considering the chest wall compression and IPV devices, there should be demonstrated need for airway clearance. There should also be documented failure of standard treatments, i.e., the patient has frequent severe exacerbations of respiratory distress involving inability to clear mucus despite standard treatment (chest physical therapy and, if appropriate, use of an oscillatory PEP device) or valid reasons why standard treatment cannot be performed, such as inability of the caregiver to perform it.

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

Cross-reference:

MP-6.022 Mechanical Insufflation-Exsufflation Device
MP-6.026 Durable Medical Equipment

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*       BlueJourney PPO*       FEP PPO**

* Refer to Durable Medical Equipment Regional Carrier (DME MAC A) Region JA Noridian Healthcare Solutions, LLC (LCD)
** Refer to FEP Medical Policy Manual MP-1.01.15 Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders. The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

Oscillatory devices are used as alternatives to the standard daily percussion and postural drainage method of airway clearance for patients with cystic fibrosis. There are several types of devices including high-frequency chest compression with an inflatable vest and oscillating positive expiratory pressure devices, such as the Flutter and Acapella devices. 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 (PEP) 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 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 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.

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 these techniques can be used as alternatives to daily percussion and postural drainage, also known as chest physical therapy or chest physiotherapy, in patients with cystic fibrosis. Daily 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.

This policy addresses outpatient use of oscillatory devices. Inpatient device use, e.g., in the immediate postsurgical period, is not included in the policy.

Mechanical percussors are electrical devices used in place of manual chest percussion to assist with mobilizing and clearing respiratory secretions. The use of these devices involves appropriate patient or operator training by a physician or therapist. According to the guidelines
developed by American Association for Respiratory Care (AARC) on postural drainage therapy, no convincing evidence demonstrates the superiority of one method over the other; however, use of a mechanical percussor can benefit the patient by allowing for independence and greater compliance.

Regulatory Status

Several oscillatory devices have been cleared for marketing by the U.S. Food and Drug Administration (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 Scandipharm.
- The ThAIRapy Bronchial Drainage System in 1998. Since that time, updated versions of the device were cleared by 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.
- The inCourage® System (Respiratory Technologies; Lakeville, MN) in 2005.
- The Vibralung Acoustical Percussor (Westmed Inc., Tucson AZ) in May 2014.

IV. RATIONALE

Cystic Fibrosis

A number of randomized controlled trials (RCTs) and a Cochrane systematic review of RCTs have evaluated oscillatory devices for the treating patients with cystic fibrosis (CF). The Cochrane review addressed a variety of oscillatory devices and was last updated in 2014.¹ Investigators identified 35 RCTs (total N=1050 patients) that compared oscillatory devices with another recognized airway clearance technique. Fifteen studies used parallel design and 20 used crossover. Ten studies included were published only as abstracts. Sixteen were conducted in the United States, and 14 of them were single-center studies. Sample sizes of individual studies ranged from 5 to 166 patients, and half the studies included children. Outcomes included pulmonary function, sputum weight and volume, hospitalization rate, and quality-of-life measures. Data could not be pooled due to the variety of devices, outcome measures, and lengths of follow-up used. The authors concluded that there is a lack of evidence supporting any specific airway clearance technique or device over another and that there is a need for adequately powered RCTs with long-term follow-up.

Representative recent RCTs follow.
In 2013, McIlwaine et al published an RCT comparing 2 types of oscillatory devices. The study differed from previous trials in several ways. It had a larger sample size (N=107) and the primary outcome measure was a clinically meaningful outcome (i.e., number of pulmonary exacerbations requiring an antibiotic). Moreover, the study was conducted over a relatively long time period (1 year), was multicenter, and was not industry-funded, although the manufacturer donated devices. The trial included individuals older than 6 years of age with clinically stable CF; age ranged from 6 to 47 years. Patients were randomized to perform positive expiratory pressure (PEP) using a face mask (n=51) or high-frequency chest wall oscillation (HFCWO) 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 but before treatment, and another 3 patients dropped out during the intervention phase. Eighty-eight (82%) of 107 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 no statistically significant difference in pulmonary measures, including forced expiratory volume in 1 second (FEV₁). Limitations of this trial were lack of patients blinding, and a nearly 20% dropout rate. The trial was also stopped early without enrolling the expected number of patients and, thus, may have been underpowered to detect clinically significant differences between groups.

In 2010, Sontag et al published a multicenter RCT with 166 adults and children with CF. Patients were assigned to receive treatment with percussion and postural drainage (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 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) percent predicted. The small sample size and high dropout rate greatly limit conclusions that might be drawn from this trial.

Pryor et al (2010) evaluated 75 patients ages 16 years and older with CF from a single center from the U.K. 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 (87%) of 75 patients completed the study and were included in the analysis. Mean (SD) 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 across 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.

Section Summary: Cystic Fibrosis
A number of RCTs and a systematic review have been published. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. The systematic review 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 systematic review concluded that additional RCTs are needed that are adequately powered and have long-term follow-up.

Bronchiectasis
In 2015, Lee et al published a Cochrane review on airway clearance techniques for treating bronchiectasis. Seven RCTs comparing airway clearance techniques with sham or an alternative treatment were identified. Sample sizes ranged from 8 to 37 patients. All studies, except 1 (N=37), were crossover trials. Five trials used a PEP device, 1 used HFCWO, and 1 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 1 trial, a crossover study with 20 patients, reported exacerbations. This trial, published by Murray et al (2009), did not find a statistically significant difference at 12 weeks in the number of exacerbations (there were 5 exacerbations with the oscillating PEP device vs 7 without the oscillating PEP device; p=0.48). 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. The study by Svenningsen et al did not. The third study, by Nicolini et al, used HFCWO and found significantly better HRQOL with the oscillatory device than with control. The Cochrane reviewers noted that the studies were not blinded and that patient-reported QOL measures may have been subject to bias.

Section Summary: Bronchiectasis
A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 reported the clinically important outcomes exacerbations or hospitalizations. Only 3 reported on QOL and trial findings were mixed.

Chronic Obstructive Pulmonary Disease
At least 2 systematic reviews of studies on airway clearance techniques in patients with chronic obstructive pulmonary disease (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 et al identified 6 studies evaluating PEP in COPD patients, 4 of which used oscillatory devices (Flutter or Cornet), and one 2007 study of 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. The authors noted 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.\textsuperscript{10}

Several randomized studies were published after the systematic reviews discussed above. Two were randomized crossover studies. Chakrovorty et al (2011) published a randomized crossover study that included patients with moderate-to-severe COPD and mucus hypersecretion.\textsuperscript{11} Patients received HFCWO or conventional treatment, in random order, for 4 weeks, with a 2-week washout 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 QOL as measured using the St. George’s Respiratory Questionnaire (SGRQ). Only 1 of 4 dimensions of the SGRQ (the symptom dimension) improved after HFCWO compared with baseline, with a decrease in 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 pre- to posttreatment differences in secondary outcomes (e.g., FEV\textsubscript{1}, FVC).

In 2016, Svenningsen et al published an unblinded, industry-funded, randomized crossover study of oscillatory PEP versus usual care in 32 COPD patients ages 40 to 85 years.\textsuperscript{12} Each intervention period lasted 21 to 28 days. Five (16\%) of 32 patients withdrew from the study; the remaining 27 patients were included in the analysis. Findings were reported separately for the subgroup of sputum-producers (n=14) and nonsputum producers (n=13) at baseline. In the nonsputum producers, there were not significant differences before and after PEP use in most outcomes, including FEV\textsubscript{1}, FVC, FEV\textsubscript{1}/FVC, 6-minute walk test (6MWT) distance, SGRQ total score, and Patient Evaluation Questionnaire (PEQ) total score. Scores differed significantly only on the PEQ ease of bringing up sputum subscale. In patients who were sputum-producers at baseline, pre versus post PEP scores differed significantly for FVC, 6MWT distance, SGRQ total score, and the PEQ ease of bring up sputum and patient global assessment subscales. There were no significant differences in FEV\textsubscript{1}, FEV\textsubscript{1}/FVC, or PEQ global score. The crossover studies had similar limitations including no between-group comparisons (i.e., outcomes after oscillatory device use vs the control intervention), lack of ITT analysis and short-term follow-up (immediate posttreatment period).

A parallel-group RCT was published in 2013 by Goktalay; it included 50 patients with stage 3 or 4 COPD hospitalized for COPD exacerbations.\textsuperscript{13} Patients were randomized to receive 5 days of treatment with medical therapy plus HFCWO (n=25) or medical therapy only (n=25). At day 5, outcomes, including FEV\textsubscript{1}, Modified Medical Research Council dyspnea scale scores, and the 6MWT distance, did not differ significantly between groups. This short-term study included hospitalized patients who may differ from COPD patients treated on an outpatient basis.

**Section Summary: Chronic Obstructive Pulmonary Disease**

Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tended to use ITT analysis and between-group comparisons. Moreover, the published studies had mixed findings and did not clearly support use of oscillatory devices in COPD patients.
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. The review included RCTs and nonrandomized comparative studies. Three studies were identified on HFCWO (1 RCT, 2 pre-post) and 1 on PEP (pre-post). Sample sizes ranged from 15 and 28 patients.

The RCT, published by Yuan et al (2010), compared HCFWO to standard chest physical therapy in 28 patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic. Both groups were instructed to perform the assigned treatment for 12 minutes 3 times a day for the study period (mean, 5 months). Twenty-three (82%) of 28 patients completed the study; all 5 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, 4 patients required inpatient intravenous antibiotics in the standard physical therapy group and none in the HCFWO group (p=0.09). In addition, 7 patients required oral antibiotics in the standard physical therapy group and 3 in the HFCWO 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, 1 RCT, published by Lange et al (2006) was identified on HFCWO in adults with amyotrophic lateral sclerosis (ALS). 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.

Section Summary: Respiratory Conditions Related to Neuromuscular Disorders

Two RCTs and a systematic review were identified evaluating oscillatory devices for treatment of respiratory conditions in neuromuscular disorders. One RCT was not powered to detect statistical significance. The other, conducted in ALS patients, did not find statistically significant improvement after HCFWO versus usual care for the primary outcomes (pulmonary function measures) or in most secondary outcomes.
**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in May 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**
For individuals who have cystic fibrosis (CF) who receive oscillatory devices, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. RCTs had mixed findings and limitations such as small sample sizes and large dropout rates. A systematic review 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 to heterogeneity in study design and outcome measures. The systematic review concluded that additional RCTs are needed that are adequately powered and have long-term follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have bronchiectasis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. A 2015 systematic review identified 7 small RCTs on several types of oscillatory devices; only 1 RCT reported the clinically important outcomes of exacerbations or hospitalizations. Only 3 RCTs reported on quality of life, and findings were mixed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic obstructive pulmonary disease (COPD) who receive oscillatory devices, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. Only a few controlled studies have evaluated oscillatory devices for the treatment of COPD, and they tend to have small sample sizes, short follow-up periods, and limitations in their analyses (e.g., lack of intention to treat analysis and between-group comparisons). Moreover, the published studies have mixed findings and do not clearly support the use of oscillatory devices in COPD patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have respiratory conditions related to neuromuscular disorders who receive oscillatory devices, the evidence includes 2 RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. One of the RCTs was not powered to detect statistical significance. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvement after high-frequency chest wall compression devices versus usual care in primary outcomes, in pulmonary function measures, or in most secondary outcomes.

**Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**
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.

In response to requests, input was received from 2 academic medical centers while this policy was under review in 2008. The reviewers indicated that the available studies demonstrated that these devices are comparable with chest physical therapy for CF and bronchiectasis. The most commonly mentioned clinical criteria were patients who failed or were intolerant of other methods of mucus clearance and patients who lacked caregivers to provide chest physical therapy. The clinical input did not support using oscillatory devices for treatment of COPD.

**Practice Guidelines and Position Statements**

**American College of Chest Physicians**
The 2006 guidelines from the American College of Chest Physicians recommended (level of evidence: low) that, in patients with CF, devices designed to oscillate gas in the airway, either directly or by compressing the chest wall, can be considered as an alternative to chest physical therapy.\(^\text{17}\)

**Cystic Fibrosis Foundation**
In 2009, the Cystic Fibrosis Foundation (CFF) published guidelines on airway clearance therapies based on a systematic review of evidence.\(^\text{18}\) CCF recommended airway clearance therapies for all patients with CF, but stated that no therapy had been demonstrated to be superior to others (level of evidence: fair; net benefit: moderate; grade of recommendation: B). CFF also issued a consensus recommendation that the prescribing of airway clearance therapies should be individualized based on factors such as age and patient preference.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

V. **DEFINITIONS**

**Chest Physical Therapy** refers to a specific type of respiratory therapy that includes manual chest percussion and postural drainage.

**Chronic Diffuse Bronchiectasis**- refers to a 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.

**510(k)** A premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

**Oscillation** is a swinging, pendulum-like movement.
VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A7025</td>
<td>High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each</td>
</tr>
<tr>
<td>A7026</td>
<td>High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each</td>
</tr>
<tr>
<td>E0480</td>
<td>Percussor, electric or pneumatic, home model</td>
</tr>
<tr>
<td>E0481</td>
<td>Intrapulmonary percussive ventilation system and related accessories</td>
</tr>
<tr>
<td>E0483</td>
<td>High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each</td>
</tr>
<tr>
<td>E0484</td>
<td>Oscillatory positive expiratory pressure device, non-electric, any type, each</td>
</tr>
<tr>
<td>S8185</td>
<td>Flutter device</td>
</tr>
</tbody>
</table>
**MEDICAL POLICY**

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>AIRWAY CLEARANCE DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP-6.015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E84.0</td>
<td>Cystic fibrosis with pulmonary manifestations</td>
</tr>
<tr>
<td>E84.11</td>
<td>Meconium ileus in cystic fibrosis</td>
</tr>
<tr>
<td>E84.19</td>
<td>Cystic fibrosis with other intestinal manifestations</td>
</tr>
<tr>
<td>E84.8</td>
<td>Cystic fibrosis with other manifestations</td>
</tr>
<tr>
<td>J41.0</td>
<td>Simple chronic bronchitis</td>
</tr>
<tr>
<td>J41.1</td>
<td>Mucopurulent chronic bronchitis</td>
</tr>
<tr>
<td>J41.8</td>
<td>Mixed simple and mucopurulent chronic bronchitis</td>
</tr>
<tr>
<td>J43.0</td>
<td>Unilateral pulmonary emphysema [MacLeod's syndrome]</td>
</tr>
<tr>
<td>J43.1</td>
<td>Panlobular emphysema</td>
</tr>
<tr>
<td>J43.2</td>
<td>Centrilobular emphysema</td>
</tr>
<tr>
<td>J43.8</td>
<td>Other emphysema</td>
</tr>
<tr>
<td>J44.0</td>
<td>Chronic obstructive pulmonary disease with acute lower respiratory infection</td>
</tr>
<tr>
<td>J44.1</td>
<td>Chronic obstructive pulmonary disease with (acute) exacerbation</td>
</tr>
<tr>
<td>J47.0</td>
<td>Bronchiectasis with acute lower respiratory infection</td>
</tr>
<tr>
<td>J47.1</td>
<td>Bronchiectasis with (acute) exacerbation</td>
</tr>
<tr>
<td>J47.9</td>
<td>Bronchiectasis, uncomplicated</td>
</tr>
<tr>
<td>Q33.4</td>
<td>Congenital bronchiectasis</td>
</tr>
</tbody>
</table>

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

**IX. REFERENCES**

5. **Lee AL, Burge AT, Holland AE. Airway clearance techniques for bronchiectasis. Cochrane Database Syst Rev. 2015;11:CD008351. PMID 26591003**

Other Sources:
Taber’s Cyclopedic Medical Dictionary 20th edition

X. POLICY HISTORY

<table>
<thead>
<tr>
<th>MP 6.015</th>
<th>CAC 2/25/03</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CAC 6/29/04</td>
</tr>
<tr>
<td></td>
<td>CAC 8/30/05</td>
</tr>
<tr>
<td></td>
<td>CAC 10/25/05</td>
</tr>
<tr>
<td></td>
<td>CAC 10/31/06</td>
</tr>
<tr>
<td></td>
<td>CAC 11/28/06</td>
</tr>
<tr>
<td></td>
<td>CAC 1/30/07</td>
</tr>
<tr>
<td></td>
<td>CAC 3/25/08</td>
</tr>
<tr>
<td></td>
<td>CAC 1/27/09</td>
</tr>
<tr>
<td></td>
<td>CAC 3/30/10 Added coverage for intrapulmonary percussive ventilation (IPV) and expanded coverage of high-frequency chest compression to include treatment of bronchiectasis</td>
</tr>
<tr>
<td></td>
<td>CAC 4/26/11 Consensus review.</td>
</tr>
<tr>
<td></td>
<td>CAC 10/25/11 Minor revision. Policy revised to add that high-frequency chest compression systems devices may be considered medically necessary for the treatment of respiratory weakness associated with neuromuscular disease.</td>
</tr>
<tr>
<td></td>
<td>CAC 8/28/12 Consensus review. No changes to policy statements; references updated. FEP variation was revised.</td>
</tr>
<tr>
<td></td>
<td>Codes reviewed 8/10/12.</td>
</tr>
<tr>
<td></td>
<td>CAC 9/30/13 Consensus review References updated but no changes to the policy statements.</td>
</tr>
<tr>
<td></td>
<td>CAC 5/20/14 Consensus. Adopting BCBSA policy statements while maintaining coverage for use of High-Frequency Chest Compression Systems in neuromuscular disease. Slight change in wording did not change intent of policy criteria. Codes reviewed</td>
</tr>
<tr>
<td></td>
<td>CAC 6/2/15 Consensus review. Reference and rationale updated. No changes to the policy statements.</td>
</tr>
<tr>
<td></td>
<td>11/2/15 Administrative change. LCD number changed from L12870 to L33785 due to NHIC update to ICD-10.</td>
</tr>
<tr>
<td></td>
<td>CAC 5/31/16 Consensus review. No change to policy statements. References and rationale updated. Changed DME Medicare carrier from NHIC to Noridian. Coding reviewed.</td>
</tr>
<tr>
<td></td>
<td>Admin update 1/1/17: Product variation section updated.</td>
</tr>
</tbody>
</table>
|         | CAC 9/27/16 Minor review. Removed minimum age 2 limitation. Added statement indicating the use of a device is to be consistent with U.S. Food
and Drug Administration (FDA) approval. Added information addressing trial period and continued use. Coding reviewed.