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

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 09/20/2017

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 and intrapulmonary percussive ventilation (IPV) devices in patients with cystic fibrosis (CF) or chronic diffuse bronchiectasis as determined by specific criteria (including chest computed tomography scan) when standard chest physical therapy has failed OR standard chest physical therapy is unavailable or not tolerated.

Note:
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.

Based on review of available data, the Company may consider the use of an oscillatory positive expiratory pressure (PEP) 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.

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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 other applications of high-frequency chest wall compression devices and intrapulmonary percussive ventilation devices, including but not limited to, their use in patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above, their use as an adjunct to chest physical therapy or their use in other lung diseases, such as chronic obstructive pulmonary disease (COPD) or respiratory conditions associated with neuromuscular disorders, to be investigational.*

Background/Overview
Oscillatory devices are designed to move mucus and clear airways; the oscillatory component can be intra- or extrathoracic. Some devices require the active participation of patients. They 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 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 airflow oscillation.

Other airway clearance techniques also require active patient participation. For example, autogenic drainage and an active cycle breathing technique both involve a combination of breathing exercises performed by the patient. Positive expiratory pressure 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.

High-frequency chest wall oscillation devices (eg, the Vest Airway Clearance System, ThAIRapy Bronchial Drainage System, SmartVest Airway Clearance System) are passive oscillatory devices designed to provide airway clearance without the active patient participation. 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 inflate and deflate the vest against the thorax, creating high-frequency chest wall oscillation and mobilization of pulmonary secretions.

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

All of these techniques may be alternatives to daily percussion and postural drainage in patients with cystic fibrosis, also known as chest physical therapy. Daily percussion and postural drainage need to be
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administered by a physical therapist or another trained adult in the home, often a parent if the patient is a child. The necessity for regular therapy can be particularly burdensome for adolescents or adults who lead independent lifestyles. Oscillatory devices can also potentially be used by patients with other respiratory disorders to promote bronchial secretion drainage and clearance, such as diffuse bronchiectasis and chronic obstructive pulmonary disease. Additionally, they could benefit patients with neuromuscular disease who have impaired cough clearance.

This evidence review addresses the outpatient use of oscillatory devices. We do not address inpatient device use (eg, in the immediate postsurgical period) here.

**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 those listed in Table 1.

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bird IPV® Noncontinuous Ventilator</td>
<td>Percussionaire Corp.</td>
<td>1989</td>
</tr>
<tr>
<td>Flutter™ Mucus Clearance Device</td>
<td>Axcan Scandipharm (for marketing in the United States)</td>
<td>1994</td>
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<tr>
<td>ThAIRapy Bronchial Drainage System (Vest® Airway Clearance System)</td>
<td>Hill-Rom</td>
<td>1998</td>
</tr>
<tr>
<td>Acapella® device</td>
<td>DHD Healthcare</td>
<td>1999</td>
</tr>
<tr>
<td>RC Cornet³ Mucus Clearing Device</td>
<td>PARI Respiratory Equipment</td>
<td>1999</td>
</tr>
<tr>
<td>inCourage® System</td>
<td>RespirTech</td>
<td>2005</td>
</tr>
<tr>
<td>AerobiKA oscillating PEP device</td>
<td>Trudell Medical</td>
<td>2013</td>
</tr>
<tr>
<td>Vibralung Acoustical Percussor</td>
<td>Westmed</td>
<td>2014</td>
</tr>
</tbody>
</table>

PEP: positive expiratory pressure.
FDA product codes: BYI, BYT.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Rationale/Source**

**CYSTIC FIBROSIS**

A number of randomized controlled trials (RCTs) and a Cochrane systematic review of RCTs have evaluated oscillatory devices for treating patients with CF. The Cochrane review addressed a variety of oscillatory devices and was last updated in 2014. Reviewers 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
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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 (QOL) measures. The overall risk of bias was unclear in about 85% of studies. Data could not be pooled due to the variety of devices, outcome measures, and lengths of follow-up used. Reviewers concluded that there was 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.

McIlwaine et al (2013) published an RCT comparing 2 types of oscillatory devices high-frequency chest wall oscillation (HFCWO) with PEP mask therapy. 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 (ie, the number of pulmonary exacerbations requiring an antibiotic). Moreover, the trial was conducted over a relatively long 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; ages ranged from 6 to 47 years. Patients were randomized to perform PEP using a face mask (n=51) or HFCWO (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 trial. 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 a lack of patient 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.

Sontag et al (2010) published a multicenter RCT enrolling 166 adults and children with CF, which compared outcomes for patients treated with postural drainage, the Flutter device, and HFCWO. 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 limited the conclusions that can be drawn from this trial.
Pryor et al (2010) evaluated 75 patients ages 16 years and older with CF from a single center in the U.K. Patients were randomized to 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 trial and were included in the analysis. Mean (standard deviation) FEV\textsubscript{1} values at 12 months (the primary outcome) were 1.90 liters (0.89) in the Cornet group (n=14), 2.43 liters (0.94) in the Flutter group (n=12), 2.02 liters (1.17) in the PEP group (n=13), 1.94 liters (0.80) in the active cycle of breathing group (n=13), and 2.64 liters (1.22) in the autogenic drainage group (n=13). The differences between the 5 groups were not statistically significant for FEV\textsubscript{1} or any other lung function variable; however, this trial had a small number of patients per group.

**Section Summary: Cystic Fibrosis**

A number of RCTs evaluating oscillatory devices have had mixed findings and limitations (eg, small sample sizes, large dropout rates). A systematic review identified 35 RCTs comparing oscillatory devices with another recognized airway clearance techniques; some were published only as abstracts. The study findings were not pooled due to heterogeneity in study designs and outcome measures. The systematic review concluded that results from additional RCTs with adequate power and long-term follow-up would permit conclusions on the effect of oscillatory devices on outcomes for cystic fibrosis.

**BRONCHIECTASIS**

Lee et al (2015) published a Cochrane review of airway clearance techniques for treating bronchiectasis. Reviewers identified 7 RCTs (total N=107 patients) comparing airway clearance techniques with sham or an alternative treatment. Sample sizes ranged from 8 to 37 patients. All studies were crossover trials, except one (N=37). Five trials used a PEP device, one used HFCWO, and one used postural drainage. Reviewers did not pool study findings due to heterogeneity among studies. Primary outcomes of interest to reviewers were exacerbations, hospitalizations for bronchiectasis, and QOL. Only 1 trial, a crossover study with 20 patients, reported exacerbations. Published by Murray et al (2009), this trial 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 QOL with a PEP device compared with control. The preliminary reporting of the study by Svenningsen et al (2013) did not. The third study (by Nicolini et al, 2013) used HFCWO and found significantly better health-related QOL with the oscillatory device than with control. Cochrane reviewers noted that the studies were not blinded and that patient-reported QOL measures may have been subject to bias.

Herrero-Cortina et al (2016) reported on a crossover RCT that included 31 patients with bronchiectasis and mean daily spontaneous sputum production of 15 mL or more. Patients received 3 week-long airway clearance interventions in random order, with a 7-day washout period between interventions. The interventions were temporary PEP, autogenic drainage, and slow expiration with the glottis opened in the lateral position. Treatment sessions occurred on 3 nonconsecutive days during the week. There were no significant differences among treatments in the mean sputum clearance during the 24-hour period after each intervention, cough severity (measured using the total Leicester Cough Questionnaire score), or in
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lung function measures (eg, FEV$_1$). Sputum production during physical therapy sessions was significantly higher in the autogenic drainage and slow expiration with the glottis opened interventions compared with the temporary PEP intervention (p<0.02).

**Section Summary: Bronchiectasis**
A 2015 systematic review identified 7 small RCTs assessing several types of oscillatory devices; only one reported the clinically important outcomes exacerbations or hospitalizations. Three reported on QOL, and trial findings were mixed. A 2016 crossover RCT did not find a significant benefit of temporary PEP compared with other airway clearance techniques.

**CHRONIC OBSTRUCTIVE PULMONARY DISEASE**
At least 2 systematic reviews have evaluated studies of airway clearance techniques in patients with COPD. Both reviews addressed various techniques (ie, 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 HFCWO. 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. Reviewers noted that the evidence on techniques such as oscillating PEP was poor due to a lack of appropriate trials. The 2012 Cochrane review of airway clearance techniques for COPD did not specifically discuss the number or the results of studies on oscillatory devices.

Several randomized studies, two of which used a crossover design, were published after the systematic reviews discussed above. Chakrovorty et al (2011) assessed 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 washout period between treatments. Thirty patients enrolled in the trial and 22 (73%) completed it; 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 SGRQ dimensions improved after conventional treatment. There were no significant pre- to posttreatment differences in secondary outcomes (eg, FEV$_1$, FVC).

Svenningsen et al (2016) published an unblinded, industry-funded, randomized crossover study comparing oscillatory PEP with usual care in 32 COPD patients aged 40 to 85 years. Each intervention period lasted 21 to 28 days. Five (16%) of 32 patients withdrew from the trial, leaving the remaining 27 patients for 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$_1$, FVC, FEV$_1$/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 bringing up sputum and patient global assessment subscales. There were no significant differences in FEV$_1$, FEV$_1$/FVC, or PEQ global score. The crossover studies had similar limitations including no
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between-group comparisons (ie, outcomes after oscillatory device use vs the control intervention), lack of ITT analysis, and short-term follow-up (immediate posttreatment period).

Goktalay et al (2013) reported on a parallel-group RCT evaluating HFCWO therapy, which included 50 patients with stage 3 or 4 COPD hospitalized for COPD exacerbations. Patients were randomized to 5 days of treatment with medical therapy plus HFCWO (n=25) or to medical therapy only (n=25). At day 5, outcomes including FEV₁, modified Medical Research Council dyspnea scale scores, and the 6MWT distance, did not differ significantly between groups. This short-term trial included hospitalized patients who might 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 support the use of oscillatory devices in COPD patients.

RESPIRATORY CONDITIONS RELATED TO NEUROMUSCULAR DISORDERS

Children
A 2014 Cochrane review of the nonpharmacologic management of respiratory morbidity in children with severe global developmental delay addressed airway clearance techniques. Reviewers included RCTs and nonrandomized comparative studies. They identified 3 studies on HFCWO (1 RCT, 2 pre-post) and one on PEP (pre-post), with sample sizes from 15 and 28 patients.

The RCT 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 trial; 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 (eg, incidence and duration of acute respiratory infection requiring inpatient or patient antibiotics, treatment-related adverse events). 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). Additionally, 7 patients required oral antibiotics in the standard physical therapy group and 3 in the HCFWO group (p=nonsignificant). No therapy-related adverse events were reported in either group. We did not identify any RCTs published after their Cochrane review on oscillatory devices in children with neuromuscular diseases.

Adults
Lange et al (2006) evaluated HFCWO in adults with amyotrophic lateral sclerosis (ALS). The trial included 46 patients with probable or definite ALS with respiratory conditions as evidenced by scores on the ALS Functional Rating Scale respiratory subscale between 6 and 11 (subscale range, 0 [complete ventilator support] to 12 [normal]). Patients were randomized to 12 weeks of HCFWO or to 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 function.
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measures (FVC predicted, capnography, oxygen saturation, or peak expiratory flow). There was also no significant difference in the ALS Functional Rating Scale 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 the noise of breathing, suction frequency, suction amount, day cough, and nocturnal symptoms.

Section Summary: Respiratory Conditions Related to Neuromuscular Disorders
We identified 2 RCTs and a systematic review 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 compared with usual care for the primary outcomes (pulmonary function measures) or for most secondary outcomes.

SUMMARY OF EVIDENCE
For individuals who have cystic fibrosis who receive oscillatory devices, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, quality of life, hospitalizations, and medication use. The 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. The review authors could not pool findings due to heterogeneity in study designs and outcome measures, and they concluded that additional adequately powered RCTs with long-term follow up are needed to make conclusions about oscillatory devices for cystic fibrosis. 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 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 (eg, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

Policy History
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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
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.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
09/23/2015 Medical Policy Implementation Committee approval. Added IPV to policy statements, replaced Flutter and Acapella with “oscillatory PEP devices” in policy statements. Updated rationale and references.
09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. Patients with respiratory conditions associated with neuromuscular disorders added to investigational statement. In title, “disorders” changed to “conditions”.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017 Medical Policy Committee review
09/20/2017 Medical Policy Implementation Committee approval. ‘Not medically necessary’ statement removed and “patients with cystic fibrosis or chronic diffuse bronchiectasis other than as specified above” added to the investigational statement.

Next Scheduled Review Date: 09/2018

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<td>E84.0, E84.11, E84.19, E84.8, E84.9, J47.0-J47.9, J67.0</td>
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*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. 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:
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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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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.

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