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

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 09/19/2018

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.to be **eligible for coverage.**

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, ie, 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.

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 air flow 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 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 1. Select Oscillatory Devices Cleared by the Food and Drug Administration

Device	Manufacturer	Clearance Date
Flutter® Mucus Clearance Device	Axcan Scandipharm (for marketing in the United States)	1994
Vest™ Airway Clearance System	Hill-Rom	1998
Acapella® device	DHD Healthcare	1999
RC Cornet™ Mucus Clearing Device	PARI Respiratory Equipment	1999
inCourage® System	RespirTech	2005
AerobiKA oscillating PEP device	Trudell Medical	2013
Vibralung Acoustical Percussor	Westmed	2014
The vest airway clearance system	Hill-Rom	2015
The Monarch™ Airway Clearance System	Hill-Rom	2017

PEP: positive expiratory pressure.

Food and Drug Administration 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

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 09/19/2018

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

CYSTIC FIBROSIS

Clinical Context and Therapy Purpose

The purpose of oscillatory PEP therapy in patients who have CF is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of oscillatory devices improve health outcomes in patients with CF?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with cystic fibrosis.

Interventions

The therapy being considered is the application of oscillatory PEP.

Comparators

The following therapy is currently being used: standard chest physical therapy.

Outcomes

The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions caused by a mucous buildup in the lungs.

Timing

Changes in outcomes over a minimum 3-month period should be considered meaningful.

Setting

Oscillatory PEP devices are intended to be used primarily in home setting by patients themselves.

Systematic Reviews

A number of 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 by Morrison and Agnew (2014) and is summarized in Table 2. 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 the superiority of oscillatory devices vs any other form of physical therapy or that 1 device was superior over another and that there is a need for adequately powered RCTs with long-term follow-up.

Table 2. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Morrison et al (2014)[1]	1995-2014	35[a]	Patients with cystic fibrosis	1050 (5-166)	RCT and controlled studies	1 wk to 1 y

[a] Ten were published only as abstracts, 16 were conducted in the United States, and 14 were single-center studies.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 3 and 4. Gaps related to relevance, study design, and conduct are summarized in Tables 5 and 6.

McIlwaine et al (2013) published an RCT comparing high-frequency chest wall oscillation (HFCWO) with PEP mask therapy. The primary outcome measure was the number of pulmonary exacerbations requiring an antibiotic. At the end of 1 year, patients in the PEP arm had a statistically significant lower incidence of pulmonary exacerbations requiring antibiotics compared with HFCWO group. The time to first pulmonary exacerbation was 220 days in the PEP group and 115 days in the HFCWO group (p=0.02). There were no statistically significant differences in pulmonary measures, including the forced expiratory volume in 1 second (FEV_1).

Sontag et al (2010) published a multicenter RCT that compared postural drainage, the Flutter device, and HFCWO. At study termination, patients had a final assessment; the length of participation ranged from 1.3 to 2.8 years. An intention-to-treat analysis found no significant differences between treatment groups in the modeled rate of decline for percent predicted FEV_1 or forced vital capacity (FVC). The small sample size and high dropout rate limited the conclusions 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. Sixty-five (87%) of 75 patients completed the trial and were included in the analysis. Although the study was described as a noninferiority trial, it was not statistically analyzed as such. Instead, no statistically significant differences among the regimens in the primary outcome measure of FEV_1 were construed as evidence for noninferiority.

Table 3. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator

Mcllwaine et al (2013)	Canada	12	2008 -2012	Children with CF age >6 y (n=107)	HFCWO (n=56)	PEP mask therapy (n=51)
Sontag et al (2010)	U.S.	20	1999-2002	Adults and children with CF (n=166)	2 active Tx: flutter (n=58) and vest (n=57)	Postural drainage (n=58)
Pryor et al (2010)	U.K.	1	NR	Patients with CF ≥16 y (n=75)	Cornet (n=15), Flutter (n=15), PEP (n=15), autogenic drainage (n=15)	Active cycle of breathing technique (n=15)

CF: cystic fibrosis; HFCWO: high- frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial; Tx: treatment.

Table 4. Summary of Key RCT Outcomes

Study	No. of PEs Requiring Antibiotics	Spirometry	Quality of Life
Mcllwaine et al (2013)[2]	88	Cannot confirm	Not applicable
HFCWO		Data not reported	Outcome not evaluated
N	96		
Median	2.00		
Range	1.00-3.00		
Positive expiratory pressure		Data not reported	Outcome not evaluated
N	49		
Median	1.00		
Range	0.00-2.00		
p	0.007	No difference	Not applicable
Sontag et al (2010)[3]			
Fulter	Outcome not evaluated	Data not reported	Outcome not evaluated
Vest	Outcome not evaluated	Data not reported	Outcome not evaluated
Postural drainage	Outcome not evaluated	Data not reported	Outcome not evaluated
p		No difference	
Pryor et al (2010)[4]	Not applicable	65	Not applicable
Active cycle of breathing techniques	Outcome not evaluated	FEV_1 at 0 mo: 2.01 FEV_1 at 12 mo: 1.94	Small improvement (0.7)[a]
Autogenic drainage	Outcome not evaluated	FEV_1 at 0 mo: 2.68 FEV_1 at 12 mo: 2.64	Small improvement (0.5)[a]
Cornet	Outcome not evaluated	FEV_1 at 0 mo: 1.93 FEV_1 at 12 mo: 1.90	No difference (<0.5)[a]
Flutter	Outcome not evaluated	FEV_1 at 0 mo: 2.46 FEV_1 at 12 mo: 2.43	Moderate improvement (1.3)[a]
Positive expiratory pressure	Outcome not evaluated	FEV_1 at 0 mo: 2.17 FEV_1 at 12 mo: 2.02	Small improvement (0.8)[a]
p	Not applicable	No difference	Not reported

FEV_1: forced expiratory volume in 1 second; HFCWO: high-frequency chest wall oscillation; PE: pulmonary exacerbations; RCT: randomized controlled trial.
[a] Minimal important differences in the Chronic Respiratory Questionnaire. A change of 0.5 represents a small difference in symptoms, 1.0 a moderate difference, and 1.5 a large difference

Table 5. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Mcllwaine et al (2013)					

Sontag et al (2010)
Pryor et al (2010)

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Follow-Up[e]	Power[d]	Statistical[f]
Mcllwaine et al (2013)	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. Eighty-eight (82%) of 107 randomized patients completed the trial. Trial limitations were a nearly 20% dropout rate.	4. Trial stopped early without enrolling expected number of patients and might have been underpowered to detect clinically significant differences between groups	
Sontag et al (2010)	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. Dropout rates were high; trial ended early: 35 (60%), 16 (31%), and 5 (9%) patients withdrew from the postural drainage, Flutter, and Vest groups, respectively. Most common reasons for withdrawal after 60 days were moved or lost to follow-up (n=13) and lack of time (n=7).	4. Trial ended earlier than planned	
Pryor et al (2010)	3. Allocation concealment unclear	1. Not blinded to treatment assignment		1. Ten of 75 randomized patients were lost to follow-up		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

FEV_1: forced expiratory volume in 1 second.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Cystic Fibrosis
A number of RCTs evaluating oscillatory devices have reported 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 designs and outcome measures. A 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 CF.

OTHER RESPIRATORY DISORDERS

Clinical Context and Therapy Purpose

The purpose of oscillatory PEP therapy in patients who have other respiratory disorders (eg, bronchiectasis, COPD, respiratory conditions related to neuromuscular disorders) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of oscillatory devices improve health outcomes in patients with other respiratory disorders (eg, bronchiectasis, COPD, respiratory conditions related to neuromuscular disorders)?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with other respiratory disorders (eg, bronchiectasis, COPD, respiratory conditions related to neuromuscular disorders).

Interventions

The therapy being considered is the application of an oscillatory PEP.

Comparators

The following therapy is currently being used: standard chest physical therapy or standard therapy.

Outcomes
The general outcomes of interest are reductions in respiratory symptoms due to airway restrictions (eg, pulmonary exacerbations).

Timing
Changes in outcomes over a minimum 3-month period should be considered meaningful.

Setting
Oscillatory PEP devices are intended to be used primarily in home setting by patients themselves.

Bronchiectasis
Lee et al (2015) published a Cochrane review of airway clearance techniques for treating bronchiectasis, which is summarized in Table 7. Of 7 RCTs included, 6 were crossover trials. 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 were pulmonary exacerbations, hospitalizations for bronchiectasis, and QOL.

Table 7. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Lee et al (2015)	1966-2015	7 RCTs	Adults and children diagnosed with bronchiectasis based on plain-film chest radiography, bronchography, high-resolution computed tomography or physician diagnosis	1107 (8-37)	1 RCT, 6 crossover RCTs	Immediate (within 24 h) and "long-term" (>24 h)

RCT: randomized controlled trial.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 8 and 9. Gaps related to relevance, study design, and conduct are summarized in Tables 10 and 11.

Murray et al (2009) reported on a crossover study with 20 patients. The number of exacerbations did not differ statistically at 12 weeks. Cough-related QOL was significantly better after 12 weeks of any airway clearance technique compared with no airway clearance. Cochrane reviewers noted that the study was not blinded, and that patient-reported QOL measures may have been subject to bias.

Herrero-Cortina et al (2016) reported on a crossover RCT with 31 patients. The interventions were temporary PEP, autogenic drainage, and slow expiration with the glottis opened in the lateral position. 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 lung function measures (eg, FEV_1).

Table 8. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator

Murray et al (2009)	U.K.	1	NR	Patients radiologically diagnosed with bronchiectasis (n=20)	Acapella Choice (n=20)	No chest physical therapy (n=20)
Herrero-Cortina et al (2016)	Spain	1	2010-2013	Patients radiologically Diagnosed with bronchiectasis (n=31)	Slow expiration with glottis opened in lateral posture (n=31) and temporary PEP (n=31)	Autogenic drainage (n=31)

NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial.

Table 9. Summary of Key RCT Outcomes

Study	Total LCQ Score Difference	24-h Sputum Volume Difference, mL	No. of Exacerbations
	Median (IQR)	**Median (IQR)**	
Murray et al (2009)	20	20	Not applicable
Acapella	1.3 (-0.17–3.25)	2 (0–6)	5
No Acapella	0 (-1.5–0.5)	-1 (-5 to to 0)	7
p	0.002	0.02	0.48
	Change (95% CI); p	**Change (95% CI)**	
Herrero-Cortina et al (2016)			
Autogenic drainage	0.5 (0.1 to 0.5); 0.01	-1.4 (5.1 to 1.2)	Not studied
ELTGOL	0.9 (0.5 to 2.1); 0.001	-1.6 (-4.8 to1.0)	Not studied
TPEP	0.4 (0.1 to 1.2); 0.04	-2.5 (-8.6 to 0.1)	Not studied
p	See above	0.01	Not applicable

CI: confidence interval; ELTGOL: expiration with glottis opened in lateral posture; IQR: interquartile range; LCQ: Leicester Cough Questionnaire; RCT: randomized controlled trial; TPEP: temporary positive expiratory pressure.

Table 10. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Murray et al (2009)					
Herrero-Cortina et al (2016)					1, 2. Only 24-h follow-up is not enough

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Follow-Up[e]	Power[d]	Statistical[f]
Murray et al (2009)	3. Allocation concealme	1. Not blinded to treatment assignment			3. Power not based on clinically important	

	nt unclear	2. Not blinded outcome assessment 3. Outcome assessed by treating physician	difference
Herrero-Cortina et al (2016)		1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician	1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

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) and are summarized in Table 12. Studies included in both the systematic reviews were largely small and none conducted a meta-analysis. Reviewers noted that quality of evidence was generally poor.

Table 12. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ides et al (2011)	1980-2008	26	Patients with COPD	659 (7-58)	Not reported	Unclear
Osadnik et al (2012)	• Inception to 2009 (PEDro) • Inception to 2011 (CAGR)	28	Participants with investigator-defined COPD, emphysema or chronic bronchitis	907 (5-96)	RCTs (parallel and crossover)	24 h to >8 wk

CAGR: Cochrane Airways Group Specialised Register of trials; COPD: chronic obstructive pulmonary disease; PEDro: Physiotherapy Evidence Database; RCT: randomized controlled trial.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 13 and 14. Gaps related to relevance, study design and conduct are summarized in Tables 15 and 16.

Chakrovorty et al (2011) reported results of a crossover RCT among 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. 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 was no significant pre- to posttreatment differences in secondary outcomes (eg, FEV_1, FVC).

Svenningsen et al (2016) reported on results of an unblinded, industry-funded, randomized crossover study. Each intervention period lasted 21 to 28 days. In the nonsputum producers, scores differed significantly only on the Patient Evaluation Questionnaire total score. In patients who were sputum-producers at baseline, pre- vs post-PEP scores differed significantly for FVC, 6-minute walk distance, SGRQ total score, and the Patient Evaluation Questionnaire ease of bringing up sputum and patient global assessment subscales. It is unclear if the interventions were clinically meaningful. The crossover studies had similar limitations including no between-group comparisons (ie, outcomes after oscillatory device use vs the control intervention), lack of intention-to-treat analysis, and short-term follow-up (immediate posttreatment period).

Goktalay et al (2013) reported on the results of a parallel-group RCT. Patients were randomized to 5 days of treatment with medical therapy plus HFCWO (n=25) or medical therapy only (n=25). At day 5, outcomes including FEV_1, modified Medical Research Council dyspnea scale scores, and the 6-minute walk 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.

Table 13. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Chakrovorty et al (2011)	U.K.	1	NR	Patients with at least 1 COPD exacerbation with FEV_1 <0.8, FEV_1/FVC <0.7, and a daily wet sputum volume of >25 mL (n=38)	SmartVest Airway Clearance System (n=22)	No SmartVest Airway Clearance System (n=22)
Svenningsen et al (2016)	Canada	1	NR	COPD patients self-identified as sputum-producers or non-sputum-producers (n=32)	Oscillatory PEP (AerobiKA device) (n=27)	No oscillatory PEP (n=27)
Goktalay et al (2013)	Turkey	1	2009-2011	Patients with stage 3 or 4 COPD hospitalized for COPD exacerbations (n=50)	HFCWO plus medical Tx (n=25)	Medical Tx only (n=25)

COPD: chronic obstructive pulmonary disease; FEV_1: forced expiratory volume in 1 second; FVC: forced vital capacity; HFCWO: high-frequency chest wall oscillation; NR: not reported; PEP: positive expiratory pressure; RCT: randomized controlled trial; Tx: treatment.

Table 14. Summary of Key RCT Outcomes

Study	SGRO Total Scores	BODE Index
Chakrovorty et al (2011)		
SmartVest	Baseline: 63End of treatment: 60	Not assessed
No SmartVest	Baseline: 62End of treatment:62	Not assessed
p	*NS*	Not applicable
Svenningsen et al (2016)		
Oscillatory positive expiratory pressure	Sputum-producers: 40 (12) Non-sputum-producers: 36	Not assessed
Control	Sputum-producers: 49Non-sputum-producers:35	Not assessed
p	0.01 (sputum-producers) 0.64 (non-sputum-producers)	Not applicable
Goktalay et al (2013)		
HFCWO plus medical treatment	Not assessed	Day 0: 7.72Day 3: 7.00Day 5: 6.44
Medical treatment only	Not assessed	Day 0: 7.72Day 3: 7.48Day 5: 7.24
p	Not applicable	Uninterpretable

BODE: body mass index, airflow obstruction, dyspnea, and exercise; HFCWO: high-frequency chest wall oscillation; RCT: randomized controlled trial; SGRO: St George's Respiratory Questionnaire.

Table 15. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Chakrovorty et al (2011)					
Svenningsen et al (2016)					
Goktalay et al (2013)					1. Not sufficient duration for benefits (short-term follow-up for 5 d)

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 16. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Follow-Up[e]	Power[d]	Statistical[f]
Chakrovorty et al (2011)	3. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded		1. High loss to follow-up or missing data: 8 out of 30	2. Power not calculated for primary outcome	

		outcome assessment 3. Outcome assessed by treating physician	withdrew due to COPD exacerbations	
Svenningsen et al (2016)	3. Allocation concealment unclear	Not blinded to treatment assignment	1. High loss to follow-up or missing data: 16% withdrew from trial	2. Power not calculated for primary outcome
Goktalay et al (2013)	1. Participants not randomly allocated 2. Allocation not concealed	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. Power calculations not reported 2. Power not calculated for primary outcome 3. Power not based on clinically important difference

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
COPD: chronic obstructive pulmonary disease.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

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 intention-to-treat analysis and between-group comparisons. The published studies reported mixed findings and did not support the use of oscillatory devices in COPD patients.

Respiratory Conditions Related to Neuromuscular Disorders
Children
A Cochrane review by Winfield et al (2014) evaluated the nonpharmacologic management of respiratory morbidity in children with severe global developmental delay treated with 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. As a result of heterogeneity, a meta-analysis was not conducted. It is summarized in Table 17.

Table 17. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Winfield et al (2014)	Inception to Nov 2013	15	Children up to 18 y with a diagnosis of severe neurologic impairment and respiratory morbidity	Not reported	RCTs and nonrandomized comparative studies	Unclear

RCT: randomized controlled trial.

Representative recent RCTs follow. Trial characteristics and results are summarized in Tables 18 and 19. Gaps related to relevance, study design and conduct are summarized in Tables 20 and 21.

Yuan et al (2010) reported results of a parallel-arm RCT. Both groups were instructed to perform the assigned treatment for 12 minutes, 3 times a day for the study period (mean, 5 months). There were no statistically significant differences between groups on primary outcomes. No therapy-related adverse events were reported in either group.

Lange et al (2006) reported on results of a parallel-arm RCT in adults with amyotrophic lateral sclerosis. Patients were randomized to 12 weeks of HCFWO or usual care. 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 amyotrophic lateral sclerosis 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.

Table 18. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Yuan et al (2010)	U.S.	1	NR	Patients with cerebral palsy or neuromuscular disease attending a pediatric pulmonary clinic (n=28)	HCFWO (n=12)	Standard chest physical therapy (n=11)
Lange et al (2006)	U.S.	6	NR	Adults with amyotrophic lateral sclerosis (n=46).	HCFWO (n=22)	No treatment (n=24)

HFCWO: high-frequency chest wall oscillation; NR: not reported; RCT: randomized controlled trial.

Table 19. Summary of Key RCT Outcomes

Study	Hospitalization/IV Antibiotics	TDI (proportion showing worsening)
Yuan et al (2010)	23	
HCFWO	0/12	Not assessed
Standard chest physical therapy	4/11	Not assessed
p	0.09	Not applicable
Lange et al (2006)	-	18

HCFWO	Not assessed	Functional impairment: 27.8% Magnitude of task: 38.9% Magnitude of effort: 27.8%
No treatment	Not assessed	Functional impairment: 43.8% Magnitude of task: 50% Magnitude of effort: 56.2%
p	Not applicable	Functional impairment: 0.331 Magnitude of task: 0.515 Magnitude of effort: 0.092

HFCWO: high- frequency chest wall oscillation; IV: intravenous; RCT: randomized controlled trial; TDI: Transitional Dyspnea Index

Table 20. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Yuan et al (2010)					
Lange et al (2006)					

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 21. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Follow-Up[e]	Power[d]	Statistical[f]
Yuan et al 2010)	1. Allocation concealment unclear	1. Not blinded to treatment assignment 2. Not blinded outcome assessment (except chest X-rays) 3. Outcome assessed by treating physician		1. High loss to follow-up or missing data 12% missing data and all in treatment group	1, 2, 3. Trial was exploratory and was not powered to detect statistically significant findings on of the primary outcomes	
Lange et al (2006)	1. Allocation not concealed	1. Not blinded to treatment assignment 2. Not blinded outcome assessment 3. Outcome assessed by treating physician		1. High loss to follow-up or missing data 15% missing data at 12 wk	2. Power not calculated for primary outcome 3. Power not based on clinically important difference	

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

HFCWO: high-frequency chest wall oscillation.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Target sample size not achieved.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Respiratory Conditions Related to Neuromuscular Disorders
Two RCTs and a systematic review have evaluated oscillatory devices for treatment of respiratory conditions in neuromuscular disorders. One RCT was not powered to detect statistical significance. The other, conducted in amyotrophic lateral sclerosis patients, did not find statistically significant improvement after HCFWO compared with usual care for the primary outcomes (pulmonary function measures) or 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 reported 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. Reviewers could not pool findings due to heterogeneity in study designs and outcome measures and concluded that additional adequately powered RCTs with long-term follow-up would be 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 one 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 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 chronic obstructive pulmonary disease, 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 reported mixed findings and did not clearly support the use

of oscillatory devices in this population. 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 statistically significant differences. The other RCT, conducted in patients with amyotrophic lateral sclerosis, did not find significant improvements after high-frequency chest wall compression devices vs 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

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Oscillatory Devices for the Treatment of Cystic Fibrosis and Other Respiratory Disorders", Policy 1.01.15, 6:2018.
2. Morrison L, Agnew J. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database Syst Rev. 2014;7:CD006842. PMID 25038719
3. McIlwaine MP, Alarie N, Davidson GF, et al. Long-term multicentre randomised controlled study of high frequency chest wall oscillation versus positive expiratory pressure mask in cystic fibrosis. Thorax. Aug 2013;68(8):746-751. PMID 23407019
4. Sontag MK, Quittner AL, Modi AC, et al. Lessons learned from a randomized trial of airway secretion clearance techniques in cystic fibrosis. Pediatr Pulmonol. Mar 2010;45(3):291-300. PMID 20146387
5. Pryor JA, Tannenbaum E, Scott SF, et al. Beyond postural drainage and percussion: Airway clearance in people with cystic fibrosis. J Cyst Fibros. May 2010;9(3):187-192. PMID 20153269
6. Lee AL, Burge AT, Holland AE. Airway clearance techniques for bronchiectasis. Cochrane Database Syst Rev. Nov 23 2015;11(11):CD008351. PMID 26591003
7. Murray MP, Pentland JL, Hill AT. A randomised crossover trial of chest physiotherapy in non-cystic fibrosis bronchiectasis. Eur Respir J. Nov 2009;34(5):1086-1092. PMID 19541717
8. Svenningsen S, Paulin G, Wheatley A, et al. Oscillating positive expiratory pressure therapy in chronic obstructive pulmonary disease and bronchiectasis [poster]. Chest. 2013;144(741A):741. PMID
9. Nicolini A, Cardini F, Landucci N, et al. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. BMC Pulm Med. Apr 04 2013;13:21. PMID 23556995
10. Herrero-Cortina B, Vilaro J, Marti D, et al. Short-term effects of three slow expiratory airway clearance techniques in patients with bronchiectasis: a randomised crossover trial. Physiotherapy. Dec 2016;102(4):357-364. PMID 26712530
11. Ides K, Vissers D, De Backer L, et al. Airway clearance in COPD: need for a breath of fresh air? A systematic review. COPD. Jun 2011;8(3):196-205. PMID 21513439
12. Osadnik CR, McDonald CF, Jones AP, et al. Airway clearance techniques for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. Mar 14 2012;3(3):CD008328. PMID 22419331
13. Chakravorty I, Chahal K, Austin G. A pilot study of the impact of high-frequency chest wall oscillation in chronic obstructive pulmonary disease patients with mucus hypersecretion. Int J Chron Obstruct Pulmon Dis. 2011;6:693-699. PMID 22259246
14. Svenningsen S, Paulin GA, Sheikh K, et al. Oscillating positive expiratory pressure therapy in chronic obstructive pulmonary disease and bronchiectasis. COPD. Feb 2016;13(1):66-74. PMID 26430763
15. Goktalay T, Akdemir SE, Alpaydin AO, et al. Does high-frequency chest wall oscillation therapy have any impact on the infective exacerbations of chronic obstructive pulmonary disease? A randomized controlled single-blind study. Clin Rehabil. Aug 2013;27(8):710-718. PMID 23503735
16. Winfield NR, Barker NJ, Turner ER, et al. Non-pharmaceutical management of respiratory morbidity in children with severe global developmental delay. Cochrane Database Syst Rev. Oct 19 2014;10(10):CD010382. PMID 25326792
17. Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. J Child Neurol. Jul 2010;25(7):815-821. PMID 20357238

18. Lange DJ, Lechtzin N, Davey C, et al. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. Neurology. Sep 26 2006;67(6):991-997. PMID 17000967
19. McCool FD, Rosen MJ. Nonpharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines. Chest. Jan 2006;129(1 Suppl):250S-259S. PMID 16428718
20. Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respir Care. Apr 2009;54(4):522-537. PMID 19327189

Policy History

Original Effective Date: 03/24/2003
Current Effective Date: 09/19/2018

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
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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

Policy # 00090
Original Effective Date: 03/24/2003
Current Effective Date: 09/19/2018

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.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2019

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 2017 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.

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:

Code Type	Code
CPT	No codes
HCPCS	A7025, A7026, E0480, E0481, E0483, E0484
ICD-10 Diagnosis	E84.0 E84.11 E84.19 E84.8 E84.9 J47.0-J47.9 J67.0

*****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:

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.