

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

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Oscillatory devices are designed to move mucus and clear airways, and can be used as alternatives to the standard daily percussion and postural drainage (P/PD) method of airway clearance for patients with cystic fibrosis, diffuse bronchiectasis and other respiratory conditions (such as chronic obstructive pulmonary disease).

There are different types of oscillatory devices, including high-frequency chest wall oscillation (HFCWO) devices, oscillating positive expiratory pressure (OPEP) devices, and intrapulmonary percussive ventilators (IPV).

- A HFCWO device is an “airway clearance device consisting of an inflatable vest connected by tubes to a small air-pulse generator.” (*Noridian LCA A52494*)
- OPEP devices uses either a high-density stainless steel ball that rests in a plastic circular cone, or a counterweighted plug and magnet, that creates 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.

- An intrapulmonary percussive ventilator (IPV) is “a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient’s chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.” (*National Coverage Determination 240.5*)

Some devices can be intra-thoracic, requiring active participation of the patient (i.e., active oscillatory devices), while others are extra-thoracic, which does not require active participation (i.e., passive oscillatory devices).

Examples of active devices include the following:

- Flutter® Mucus Clearance Device (Axcan Scandipharm, Inc.)
- The Acapella® device (DHD Healthcare)
- RC-Cornet™ Mucus Clearing Device (PARI Respiratory Equipment)

Examples of passive devices include the following:

- Intrapulmonary Percussive Ventilation (IPV, Bird IPV®) devices (Percussionaire Corp.)
- Vest® Airway Clearance System (formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System), which provides high-frequency chest compression using an inflatable vest and an air-pulse generator (Hill-Rom)
- The inCourage® System (Respiratory Technologies, Inc.)

MEDICARE ADVANTAGE POLICY CRITERIA

Note:

- This policy does not address positive expiratory pressure (PEP) devices (e.g., the Flutter® valve, RC-Cornet™, or Acapella® devices), as they are considered medically necessary.
- This policy addresses outpatient use of oscillatory devices. Inpatient device use e.g., in the immediate post-surgical period, is not included within the scope of this policy.

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	For <i>intrapulmonary percussive ventilation system (i.e., Intrapulmonary Percussive Ventilation [IPV, Bird IPV®] devices, HCPCS code E0481):</i> ✓ Intrapulmonary Percussive Ventilator (IPV) (240.5)(See also the Noridian LCD for Intrapulmonary Percussive Ventilation System [L33786]) ^[1]
Noridian Healthcare Solutions (Noridian) Local	For <i>high frequency chest wall oscillation air-pulse generator system (i.e., Vest® Airway Clearance System</i>

Coverage Determinations (LCDs) and Articles (LCAs)*

[formerly known as the ABI Vest or the ThAIRapy Bronchial Drainage System], HCPCS code E0483), as well as replacement vests and hoses (HCPCS A7025, A7026):

- ✓ High Frequency Chest Wall Oscillation Devices ([L33785](#))

(See also the Noridian LCA for High Frequency Chest Wall Oscillation Devices - Policy Article [A52494])^[2]

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- The type of oscillatory device requested (IPV, HFCWO, OPEP, etc.); and,
- There must be information in the medical record which describes underlying medical condition(s) that cause the accumulation of pulmonary secretions, other trialed treatment interventions (for example, chest physiotherapy, postural drainage, medications used, mechanical modalities such as in-exsufflation devices, etc.) and the effectiveness of the treatment.

REGULATORY STATUS

DEVICE	MANUFACTURER	FDA Number
THE FOLLOWING DEVICES ARE EXAMPLES OF INTRAPULMONARY PERCUSSIVE VENTILATION (IPV) OR HIGH-FREQUENCY CHEST WALL OSCILLATION (HFCWO) DEVICES		
ABI® Vest System (HFCWO)	American Biosystems, Inc.	K993629
AffloVest (HFCWO)	International Biophysics Corporation	K122480
Bird IPV® (IPV)	Percussionaire Corp	K895485
SmartVest® SQL® System (HFCWO)	Electromed, Inc.	K132794
SmartVest SV2100 System (HFCWO)	Electromed, Inc.	K053248
Vest® Airway Clearance System (HFCWO)	Hill Rom	K142482, K024309

ThAIRaphy® (HFCWO)	American Biosystems, Inc.	K965192
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THE FOLLOWING DEVICES ARE EXAMPLES OF OSCILLATORY POSITIVE EXPIRATORY PRESSURE (PEP/OPEP) DEVICES, WHICH ARE NOT ADDRESSED IN THIS POLICY AND ARE CONSIDERED MEDICALLY NECESSARY.

Acapella®	Smiths Medical, Inc.	K002768
Aerobika Oscillating Positive Expiratory Pressure (OPEP)	Trudell Medical	K123400
Aerobika OPEP with Manometer	Trudell Medical	K150173
Aerosure Medic	Actegy Ltd	K140772
Flutter® Mucus Clearance Device	Axcan Scandipharm, Inc.	K946083, K940986, K972859
Lung Flute®	Medical Acoustics LLC	K091557
MetaNeb® 4 System	Hill-Rom	K151689
RC-Cornet™	PARI Respiratory Equipment	K983308
VibraPEP™	Curaplex	K153441
Roadrunner	DHD Healthcare	K991561
PARI PEP	PARI Respiratory Equipment	K972042
PARI PEP S Positive Expiratory Pressure Device	PARI Respiratory Equipment	K090829
TheraPEP®	Smiths Medical, Inc.	K944900, K962749, K983467
Vibralung Acoustical Percussor	Westmed Inc.	K133057

CROSS REFERENCES

[None](#)

REFERENCES

1. Noridian LCD for Intrapulmonary Percussive Ventilation System ([L33786](#)) (**Scroll to the “All Versions” section at the bottom of the LCD to access prior versions.)
2. Noridian LCA for High Frequency Chest Wall Oscillation Devices - Policy Article ([A52494](#)) (**Scroll to the “All Versions” section at the bottom of the LCA to access prior versions.)

CODING

Codes	Number	Description
CPT	None	
HCPCS	A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each

Codes	Number	Description
	A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each
	E0481	Intrapulmonary percussive ventilation system and related accessories <i>(Noncovered by Medicare)</i>
	E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.