Airway Clearance Devices

Humana®

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Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

Durable Medical Equipment

Description

Individuals with impaired ability to cough due to respiratory muscle weakness or pulmonary restriction have difficulty clearing secretions from the lungs. The accumulated secretions may allow growth of pathogens, leading to a higher risk for chronic infections and deterioration of lung function as the bronchial tubes can be occluded. Conditions that can lead to this problem include amyotrophic lateral sclerosis (ALS), bronchiectasis, cystic fibrosis (CF), muscular dystrophy, myasthenia gravis and spinal cord injuries.

Airway clearance devices are an alternative to standard manual chest physiotherapy (CPT), which includes percussion, postural drainage, forced expiratory maneuvers, huffing and coughing. These techniques usually require the aid of another individual. Several types of airway clearance devices have been developed, which include, but may not be limited to:

- **High-frequency chest compression vests** – These consist of an air generator and an inflatable vest that covers the chest. Increases in air pulses are delivered to the vest with oscillating airflow patterns, causing external manipulations of the chest. Examples of these devices include, but may not be limited to,

AffloVest, **InCourage System**, **Monarch Airway Clearance System**, **SmartVest Airway Clearance System**, **SmartVest SQL Airway Clearance System** and **Vest Airway Clearance System**.

- **Intrapulmonary percussive ventilation (IPV)** – IPV utilizes a mouthpiece to deliver mini bursts of oxygen while also delivering therapeutic aerosols through a nebulizer. The intended purpose of this treatment is that through a combination of bursts of oxygen and medication, it loosens secretions, stimulates cough and increases sputum production. An example of this type of device includes, but may not be limited to, the **Impulsator**. **(Refer to Coverage Limitations section)**

- **Mechanical insufflation-exsufflation (MIE)** – This approach utilizes portable devices with a facemask that covers the nose and mouth, delivering alternating positive and negative pressure allowing air to be pumped into the lungs and then rapidly evacuated. This produces a high expiratory flow rate from the lungs and stimulates a cough and increasing secretion clearance. Examples of these include, but may not be limited to, **BiWaze Cough System**, **CoughAssist** (discontinued September 2023) and **Synclara**.

- **Mechanical percussors** – These electrical devices provide clapping, percussion and/or vibration to the external chest wall and are used in place of manual chest percussion to assist with secretion clearance. Examples of these types of devices include, but may not be limited to, **Frequencer** and **Vibralung Acoustic Processor**.

- **Oscillating (vibratory) positive expiratory pressure devices (OPEP)** – These hand-held devices combine PEP with high-frequency air flow oscillations using a stainless-steel ball or a counterweight plug and magnet. These devices utilize deep breathing and forced exhalation to create a vibration of the airway walls which loosen secretions. An example of this type of device includes, but may not be limited to, **Flutter**.

  Acapella and **Aerobika** are examples of other OPEP devices; however, these devices are available over the counter without a prescription. **(Refer to Coverage Limitations section)**

- **Positive expiratory pressure (PEP) devices** – These devices increase resistance to expiratory airflow which helps improve secretion clearance by creating pressure in the lungs and preventing airway closure. The individual breathes into the device normally but breathes out harder against resistance. An example of this device includes, but may not be limited to, **Pari Pep S**.

  TheraPEP is another PEP device; however, this device is available over the counter without a prescription. **(Refer to Coverage Limitations section)**

The **Volara System** and **BiWaze Clear System** combine several noninvasive therapies into one device. These devices purportedly provide oscillation and lung expansion (OLE) therapy using PEP, oscillation and delivery of aerosol medications.[19] Volara was voluntarily recalled by the manufacturer on April 26, 2022 due to the risk of respiratory distress in ventilated patients during home use with the US Food & Drug Administration (FDA) categorizing it as a Class I recall.[50] **(Refer to Coverage Limitations section)**

Coverage Determination

Humana members may be eligible under the Plan for the following types of **airway clearance devices** for an individual diagnosed with conditions that cause the lungs to produce excessive amounts of mucous and who have difficulty clearing secretions (eg, bronchiectasis, CF or neuromuscular diseases with impaired clearance of secretions***):

- Mechanical percussors **(E0480)**
- PEP devices **(E1399)**
- OPEP devices **(E0484, S8185)**

Mechanical Insufflation-Exsufflation Devices (E0482, A7020)
Humana members may be eligible under the Plan for an **MIE device** when the following criteria are met:

- Individual with impaired ability to cough due to respiratory muscle weakness or pulmonary restriction (eg, ALS, muscular dystrophy, myasthenia gravis, poliomyelitis and spinal cord injuries);

AND either of the following:

  - Individual can no longer be adequately treated with standard manual chest physiotherapy (eg, unable to clear retained secretions); **OR**

  - Standard manual chest physiotherapy is contraindicated for the individual's condition

High-Frequency Chest Compression Vests (94669, A7025, A7026, E0483)
Humana members may be eligible under the Plan for an FDA-approved **high-frequency chest compression vest** when **ALL** of the following criteria are met:

- Absence of contraindications; **AND**

- A prescribed order for chest physiotherapy at least twice daily; **AND**

- Failure, intolerance or contraindication to alternative airway clearance methods****; **AND**

- Use of the **Monarch Airway Clearance System** requires the individual to be 15 years of age or older[49]; **AND**

- For treatment of the following:

  - Bronchiectasis confirmed by computed tomography (CT) scan and the following:

    - Daily productive cough for at least 6 consecutive months; **OR**

    - Documentation of at least 3 separate exacerbation episodes that required antibiotic therapy within the prior 12 months; **OR**

  - CF with the following:

- Ability to use vest without assistance (eg, older pediatric individuals and adults) when family members or other resources are unable to deliver prescribed therapy; **OR**

- One or more of the following **neuromuscular diseases with impaired clearance of secretions***:
  - Acid maltase deficiency; **OR**
  - Acquired or congenital myopathies affecting respiratory system (eg, centronuclear, mitochondrial or nemaline myositis, polymyositis); **OR**
  - Anterior horn cell diseases, including ALS; **OR**
  - Multiple sclerosis; **OR**
  - Muscular dystrophy; **OR**
  - Myotonic disorders (eg, channelopathies, myotonia congenita, myotonic muscular dystrophy); **OR**
  - Paralysis of the diaphragm; **OR**
  - Post-polio; **OR**
  - Quadriplegia

****Alternative airway clearance methods include the following:**

- Breathing techniques (eg, active cycle of breathing technique [ACBT], assisted inflation maneuvers, autogenic drainage, stacked breaths); **OR**
- Cough assist (manual assist, quad cough); **OR**
- Huff coughing; **OR**
- Hypertonic saline; **OR**
- Manual or percussor chest physiotherapy; **OR**
- MIE; **OR**
- Mucomyst; **OR**
- PEP/OPEP; **OR**
- Postural drainage; **OR**

- Suctioning

Coverage for **high-frequency chest compression vests** may begin with a 3 month trial of device rental if the above criteria are met. At the end of the 3 month trial period, review of physician documentation regarding compliance with prescribed therapy and stable or improved respiratory status will be required. If it is determined that continued therapy is medically necessary, device rental may be extended until 13 months, at which time it may be purchased. Coverage will extend up to limitations and exclusions found in the member's individual certificate.

Telecommunication or wireless transmission for high-frequency chest wall compression compliance is considered integral to the prescribed use of the device and not separately reimbursable.

Note: It is the Plan's option to determine if the durable medical equipment (DME) item shall be rented or purchased. If the cost of renting the item is more than the cost to buy it, only the cost of the purchase is considered to be a covered expense. In either case (rent or purchase), total covered expenses shall not exceed the purchase price. In the event the Plan determines to purchase the DME, any amount paid as rent for such equipment will be credited toward the purchase price.

There is a limit of one approved air pulse generator per member. Additional vests may be covered if original vest no longer fits appropriately due to sizing changes (eg, child has outgrown vest).

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **airway clearance devices** for any indications other than those listed above. All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **high-frequency chest compression vests** for any of the following:

CONTRAINDICATIONS[3]
Applicable to high-frequency chest compression vests or manual chest physiotherapy

Absolute Contraindications
- Active hemorrhage with hemodynamic instability; **OR**
- Head and neck injury until stabilized

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Relative Contraindications

- Active hemoptysis; **OR**
- Acute spinal injury; **OR**
- Bronchopleural fistula; **OR**
- Bronchospasm; **OR**
- Burns, open wounds or skin infections of the thorax; **OR**
- Cardiac pacemaker and/or defibrillator placement within the past 90 days (requires documentation by the physician who performed the procedure that a high-frequency chest compression vest or manual CPT is appropriate); **OR**
- Chest wall pain; **OR**
- Coagulopathy; **OR**
- Confused or anxious individual; **OR**
- Empyema; **OR**
- Epidural spinal infusion or spinal anesthesia within the past 90 days (requires documentation by the physician who performed the procedure that a high-frequency chest compression vest or manual CPT is appropriate); **OR**
- Intracranial pressure (ICP) greater than 20 mm Hg; **OR**
- Large pleural effusions; **OR**
- Lung contusion; **OR**
- Osteomyelitis of the ribs; **OR**
- Osteoporosis; **OR**
- Pulmonary edema associated with congestive heart failure; **OR**
- Pulmonary embolism; **OR**
- Rib fracture, with or without flail chest; **OR**
- Skin grafts or flaps on the thorax within the past 90 days (requires documentation by the physician who performed the procedure that a high-frequency chest compression vest or manual CPT is appropriate); **OR**

- Spinal surgery (eg, laminectomy) within the past 90 days (requires documentation by the physician who performed the procedure that a high-frequency chest compression vest or manual CPT is appropriate); **OR**

- Subcutaneous emphysema; **OR**

- Surgical wound or healing tissue on the thorax; **OR**

- Suspected pulmonary tuberculosis; **OR**

- Uncontrolled airway at risk for aspiration (eg, tube feeding)

This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Duplicate Equipment
Rental or purchase of more than one **high-frequency chest compression vest** at a time is considered duplicate and may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage for duplicate or similar equipment, which includes, but may not be limited to, equipment with the same function for use in another location (eg, school, second residence, travel, work) as it may be excluded by certificate. In the absence of a certificate exclusion, this is considered not medically necessary as defined in the member's individual certificate.

Humana members may **NOT** be eligible under the Plan for **Acapella, Aerobika (E0484) or TheraPEP (E1399)**. Although these devices may be prescribed by a health care practitioner, these devices are also available without a prescription and may be obtained over the counter (OTC) and are therefore generally excluded in the certificate. In the absence of a certificate exclusion for OTC items, these devices are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **BiWaze Clear System (E1399), IPV (E0481)** or **Volara (E1399).** These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments

94669	Mechanical chest wall oscillation to facilitate lung function, per session	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
A7020	Interface for cough stimulating device, includes all components, replacement only	
A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each	
A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each	
E0480	Percussor, electric or pneumatic, home model	
E0481	Intrapulmonary percussive ventilation system and related accessories	**Not Covered**
E0482	Cough stimulating device, alternating positive and negative airway pressure	
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each	
E0484	Oscillatory positive expiratory pressure device, nonelectric, any type, each	**Not Covered if used to report any device outlined in Coverage Limitations section**
E1399	Durable medical equipment, miscellaneous	**Not Covered if used to report any device outlined in Coverage Limitations section**
S8185	Flutter device	**Not Covered if used to report any device outlined in Coverage Limitations section**

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Change Summary

- 03/28/2024 Annual Review, No Coverage Change.