KAISER PERMANENTE® Mid-Atlantic States	**High Frequency Chest Wall Oscillation (HFCWO) and Airway Oscillating Devices** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- If, after searching the Medicare Coverage Database, no NCD/LCD/LCA is found, please use this KP-MAS Medical Coverage Policy for coverage guidelines for Medicare members.

I. Service: High Frequency Chest Wall Oscillation (HFCWO) Device and Airway Oscillating Devices

II. Specialty: Pulmonary Medicine

III. High Frequency Chest Wall Oscillation (HFCWO) Device

A. Clinical Indications for HFCWO Referral

HFCWO is considered medically necessary when **ALL** of the following criteria are met.

1. A confirmed diagnosis of any of the following:
   - **a. Cystic fibrosis**
   - **b. Immotile cilia syndrome (also known as primary ciliary dyskinesia)**
   - **c. Bronchiectasis**
     When diagnosis is confirmed by a high resolution, spiral, or standard CT scan and characterized by:
     - i. Daily productive cough for at least 6 continuous months; **or**
     - ii. Frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy.
     - Chronic bronchitis and chronic obstructive pulmonary disease (COPD) without a confirmed diagnosis of bronchiectasis does not meet this criterion
   - **d. One of the following neuromuscular diseases:**
     - i. Post-polio syndrome;
     - ii. Acid maltase deficiency;
     - iii. Anterior horn cell disease;
     - iv. Multiple sclerosis;
     - v. Quadriplegia;
     - vi. Hereditary muscular dystrophy;
     - vii. Spinal muscular dystrophy;
     - **viii.** Myotonic disorders;
     - **ix.** Other Myopathies; **or**
     - x. Paralysis of the diaphragm

2. There is documentation of failure, intolerance, or contraindication to effectively clear retained mucous in the airway with standard or less intensive treatments (such as chest physiotherapy, mucolytic agents, postural drainage, mechanical modalities i.e., exsufflation devices);
3. There is no absolute contraindication for external manipulation of the thorax including absence of the following:
   a. Active hemorrhage with hemodynamic instability;
   b. Injury to the head and/or neck that has not yet been stabilized; **or**
   c. Acute respiratory distress or failure.
4. The patient has adequate physiological cough reflex; **and**
5. The device is FDA approved or has not been recalled by FDA.

B. HFCWO device is considered *not* medically necessary for any condition not listed in section III, A due to insufficient evidence of efficacy for these indications or their effectiveness has not been established.

C. Continuation of HCFWO Treatment

1. Re-authorization of HFCWO is medically necessary if the member meets all the criteria for the base device with documentation of favorable outcome from HFCWO prior to treatment extension.
2. Approval to continue with HFCWO treatment will be denied as not reasonable and necessary if all the criteria for HFCWO are not met.

D. Contraindications and Exclusions

HFCWO is contraindicated for the following conditions:

1. Chest wall pain;
2. Lung contusion;
3. Rib fractures;
4. Acute bronchospasm;
5. Suspected pulmonary tuberculosis;
6. Osteomyelitis of the ribs;
7. Osteoporosis;
8. Osteogenesis imperfecta or other brittle bone disease(s);
9. Coagulopathy;
10. Subcutaneous emphysema;
11. Recent abdominal surgery;
12. Recent gastrostomy tube placement;
13. Recent spinal anesthesia or epidural spinal infusion;
14. Recent placement of indwelling venous catheter in the chest wall;
15. Intravenous access to an indwelling venous catheter unless the site like portacath is covered with padding;
16. Recently placed transvenous or subcutaneous pacemaker or any implanted device in the chest or chest wall;

17. Open wounds, skin infection or burns of the thorax.
18. Recent skin grafting to the chest/thorax; **and**
19. Recent esophageal surgery

E. HFCWO is considered investigational or experimental and not covered:

1. For other conditions & lung diseases, including but not limited to chronic obstructive pulmonary disease (COPD) and chronic bronchitis without a diagnosis of bronchiectasis;
2. As an adjunct to chest physical therapy;
3. The HFCWO and mechanical insufflation device are used at the same time; **and**
4. The HFCWO device has not received FDA approval specific to its indication

IV. Oscillatory Positive Expiratory Pressure Devices (e.g., Flutter valve and Acapella)

A. Clinical Indications for Referral

An airway oscillating device is considered medically necessary in the presence of ALL of the following:

1. A confirmed diagnosis of any of the following that require assisted mucus clearance:
   a. Cystic fibrosis (CF);
   b. Immotile cilia syndrome (primary ciliary dyskinesia)
   c. Bronchiectasis;
   d. Chronic Bronchitis;
   e. Asthma; **or**
   f. Chronic Obstructive Pulmonary Disease (COPD);
2. Recurrence of hypersecretory lung disease exacerbation

B. Exclusions/Limitations

An oscillatory positive expiratory pressure device is considered not medically necessary for any other condition not listed in section IV; A due to insufficient evidence of efficacy.

V. Benefits

The DME coverage of these devices is determined by the member specific benefit plan and any applicable laws to cover specific services.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC*	Date of Implementation
08/28/2019	08/28/2019
10/29/2019	10/29/2019
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10/19/2021	10/19/2021
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*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.