Airway Clearance Devices (for Ohio Only)

Policy Number: CS054OH.C
Effective Date: April 1, 2025

➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Note: For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions.

For medical necessity clinical coverage criteria of high-frequency chest wall oscillation (HFCWO) devices, refer to the Ohio Administrative Code, Rule 5160-10-08, DMEPOS: high-frequency chest wall oscillation (HFCWO) devices.

For medical necessity clinical coverage criteria for an intrapulmonary percussive ventilation system, refer to the InterQual® CP: Durable Medical Equipment, Airway or Secretion Clearance Devices.

Click here to view the InterQual® criteria.

Combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary.

Coverage Limitations and Exclusions

For coverage limitations and exclusions, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions and the Ohio Administrative Code, Rule 5160-10-02, DMEPOS: repair.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and

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applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)
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
E0469	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device
E0481	Intrapulmonary percussive ventilation system and related accessories
E0483	High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each

Clinical Evidence

Combination Continuous Positive Expiratory Pressure (CPEP), Continuous High Frequency Oscillation (CHFO), and Nebulized Medication Therapy Devices for Oscillation and Lung Expansion (OLE)

Due to insufficient quality evidence or consistency of findings, combination CPEP, CHFO, and nebulized medication therapy devices for OLE are considered unproven and not medically necessary.

Main and Rand (2023) conducted a systematic review and meta-analysis to evaluate the effectiveness (in terms of respiratory function, respiratory exacerbations, exercise capacity) and acceptability (in terms of individual preference, adherence, quality of life) of conventional chest physiotherapy (CCPT) for people with cystic fibrosis (CF) compared to alternative airway clearance techniques (ACTs). The authors included randomized or quasi-randomized controlled trials (including cross-over design) lasting at least seven days and comparing CCPT with alternative ACTs in people with CF. Primary outcomes were 1. pulmonary function tests and 2. number of respiratory exacerbations per year. Secondary outcomes were 3. quality of life, 4. adherence to therapy, 5. cost-benefit analysis, 6. objective change in exercise capacity, 7. additional lung function tests, 8. ventilation scanning, 9. blood oxygen levels, 10. nutritional status, 11. mortality, 12. mucus transport rate, and 13. mucus wet or dry weight. Outcomes were reported as short-term (seven to 20 days), medium-term (more than 20 days to up to one year) and long-term (over one year). A total of 21 (778 participants) studies comprising seven short-term, eight medium-term and six long-term studies were included. Studies were conducted in the USA (10), Canada (five), Australia (two), the UK (two), Denmark (one) and Italy (one) with a median of 23 participants per study (range 13 to 166). Participant ages ranged from newborns to 45 years; most studies only recruited children and young people. Sixteen studies reported the sex of participants (375 males; 296 females). Most studies compared modifications of CCPT with a single comparator, but two studies compared three interventions, and another compared four interventions. The interventions varied in the duration of treatments, times per day and periods of comparison making meta-analysis challenging. All evidence was very low certainty. Nineteen studies reported the primary outcomes forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) and found no difference in change from baseline in FEV1 % predicted or rate of decline between groups for either measure. Most studies suggested equivalence between CCPT and alternative ACTs, including positive expiratory pressure (PEP), extrapulmonary mechanical percussion, active cycle of breathing technique (ACBT), oscillating PEP devices (O-PEP), autogenic drainage (AD) and exercise. Where single studies suggested superiority of one ACT, these findings were not corroborated in similar studies; pooled data generally concluded that effects of CCPT were comparable to those of alternative ACTs. CCPT versus PEP: The authors are uncertain whether CCPT improves lung function or has an impact on the number of respiratory exacerbations per year compared with PEP (both very low-certainty evidence). There were no analyzable data for secondary outcomes, but many studies provided favorable narrative reports on the independence achieved with PEP mask therapy. CCPT versus extrapulmonary mechanical percussion: The authors are uncertain whether CCPT improves lung function compared with extrapulmonary mechanical percussions (very low-certainty evidence). The annual rate of decline in average forced expiratory flow between 25% and 75% of FVC (FEF25-75) was greater with high-frequency chest compression compared to CCPT in medium- to long-term studies, but there was no difference in any other outcome. CCPT versus ACBT: The authors are uncertain whether CCPT improves lung function compared to ACBT (very low-certainty evidence). Annual decline in FEF25-75 was worse in participants using the FET component of ACBT only [mean difference (MD) 6.00, 95% confidence interval (CI) 0.55 to 11.45; 1 study, 63 participants; very low-certainty evidence]. One short-term study reported that directed coughing was as effective as CCPT for all lung function outcomes, but with no

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analyzable data. One study found no difference in hospital admissions and days in hospital for exacerbations. CCPT versus O-PEP: The authors are uncertain whether CCPT improves lung function compared to O-PEP devices (Flutter device and intrapulmonary percussive ventilation); however, only one study provided analyzable data (very low-certainty evidence). No study reported data for number of exacerbations. There was no difference in results for number of days in hospital for an exacerbation, number of hospital admissions and number of days of intravenous antibiotics; this was also true for other secondary outcomes. CCPT versus AD: The authors are uncertain whether CCPT improves lung function compared to AD (very low-certainty evidence). No studies reported the number of exacerbations per year; however, one study reported more hospital admissions for exacerbations in the CCPT group (MD 0.24, 95% CI 0.06 to 0.42; 33 participants). One study provided a narrative report of a preference for AD. CCPT versus exercise: The authors are uncertain whether CCPT improves lung function compared to exercise (very low-certainty evidence). Analysis of original data from one study demonstrated a higher FEV1 % predicted (MD 7.05, 95% CI 3.15 to 10.95; p = 0.0004), FVC (MD 7.83, 95% CI 2.48 to 13.18; p = 0.004) and FEF25-75 (MD 7.05, 95% CI 3.15 to 10.95; p = 0.0004) in the CCPT group; however, the study reported no difference between groups (likely because the original analysis accounted for baseline differences). The authors concluded that they are uncertain whether CCPT has a more positive impact on respiratory function, respiratory exacerbations, individual preference, adherence, quality of life, exercise capacity and other outcomes when compared to alternative ACTs as the certainty of the evidence is very low. There was no advantage in respiratory function of CCPT over alternative ACTs, but this may reflect insufficient evidence rather than real equivalence. Narrative reports indicated that participants prefer self-administered ACTs. This review is limited by a paucity of well-designed, adequately powered, long-term studies. This review cannot yet recommend any single ACT above others; physiotherapists and people with CF may wish to try different ACTs until they find an ACT that suits them best.

Morrison and Milroy (2020) conducted a systematic review and meta-analysis to identify whether oscillatory devices, oral or chest wall, are effective for mucociliary clearance and whether they are equivalent or superior to other forms of airway clearance in the successful management of secretions in people with cystic fibrosis (CF). Search criteria included randomized controlled studies and controlled clinical studies of oscillating devices compared with any other form of physiotherapy in people with cystic fibrosis. Single-treatment interventions (therapy technique used only once in the comparison) were excluded. Two authors independently applied the inclusion criteria to publications, assessed the quality of the included studies and assessed the evidence using GRADE. The searches identified 82 studies (330 references); 39 studies (total of 1,114 participants) met the inclusion criteria. Studies varied in duration from up to one week to one year; 20 of the studies were cross-over in design. The studies also varied in type of intervention and the outcomes measured, data were not published in sufficient detail in most of these studies, so meta-analysis was limited. Few studies were considered to have a low risk of bias in any domain. It is not possible to blind participants and clinicians to physiotherapy interventions, but 13 studies did blind the outcome assessors. The quality of the evidence across all comparisons ranged from low to very low. Forced expiratory volume in one second was the most frequently measured outcome and while many of the studies reported an improvement in those people using a vibrating device compared to before the study, there were few differences when comparing the different devices to each other or to other airway clearance techniques. One study identified an increase in frequency of exacerbations requiring antibiotics whilst using high frequency chest wall oscillation when compared to positive expiratory pressure (low-quality evidence). There were some small but significant changes in secondary outcome variables such as sputum volume or weight, but not wholly in favor of oscillating devices and due to the low- or very low-quality evidence, it is not clear whether these were due to the particular intervention. Participant satisfaction was reported in 13 studies but again with low- or very low-quality evidence and not consistently in favor of an oscillating device, as some participants preferred breathing techniques or techniques used prior to the study interventions. The results for the remaining outcome measures were not examined or reported in sufficient detail to provide any high-level evidence. The authors concluded that there was no clear evidence that oscillation was a more or less effective intervention overall than other forms of physiotherapy; furthermore, there was no evidence that one device is superior to another. The findings from one study showing an increase in frequency of exacerbations requiring antibiotics whilst using an oscillating device compared to positive expiratory pressure may have significant resource implications. More adequately powered long-term randomized controlled trials are necessary and outcomes measured should include frequency of exacerbations, individual preference, adherence to therapy and general satisfaction with treatment. Increased adherence to therapy may then lead to improvements in other parameters, such as exercise tolerance and respiratory function. Additional evidence is needed to evaluate whether oscillating devices combined with other forms of airway clearance is efficacious in people with cystic fibrosis. There may also be a requirement to consider the cost implication of devices over other forms of equally advantageous airway clearance techniques. Using the GRADE method to assess the quality of the evidence, we judged this to be low or very low quality, which suggests that further research is very likely to have an impact on confidence in any estimate of effect generated by future interventions.

Huynh et al. (2019) conducted a multicenter, non-randomized prospective study to examine the impact of oscillation and lung expansion (OLE) therapy, using continuous high-frequency oscillation and continuous positive expiratory pressure on post-operative pulmonary complications (PPCs) in high-risk patients. In stage I, CPT and ICD codes were queried for patients (n = 210) undergoing thoracic, upper abdominal, or aortic open procedures at 3 institutions from December 2014

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to April 2016. Patients were selected randomly. Age, comorbidities, American Society of Anesthesiologists physical status classification scores, and PPC rates were determined. In stage II, 209 subjects were enrolled prospectively from October 2016 to July 2017 using the same criteria. Stage II subjects received OLE treatment and standard respiratory care. The PPCs rate (prolonged ventilation, high-level respiratory support, pneumonia, ICU readmission) were compared. The authors also compared ICU length of stay (LOS), hospital LOS, and mortality using t-tests and analysis of covariance. Data are mean ±SD. There were 419 subjects. Stage II patients were older (61.1 ±13.7 years vs. 57.4 ±15.5 years; $p < 0.05$) and had higher American Society of Anesthesiologists scores. Treatment with OLE decreased PPCs from 22.9% (stage I) to 15.8% (stage II) ($p < 0.01$ adjusted for age, American Society of Anesthesiologists score, and operation time). Similarly, OLE treatment reduced ventilator time (23.7 ±107.5 hours to 8.5 ±27.5 hours; $p < 0.05$) and hospital LOS (8.4 ±7.9 days to 6.8 ±5.0 days; $p < 0.05$). No differences in ICU LOS, pneumonia, or mortality were observed. The authors concluded that aggressive treatment with OLE reduces PPCs and resource use in high-risk surgical patients. Well designed, adequately powered, prospective, controlled clinical trials of combination OLE treatment are needed to further describe safety and clinical efficacy.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

High-Frequency Chest Wall Compression Devices

High-frequency chest wall compression devices are designed to promote airway clearance and improve bronchial drainage. They are indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport. Refer to the following website for more information (use product code BYI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 18, 2024)

References

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Ohio Administrative Code/5160/Chapter 5160-10-01. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-02. Accessed October 17, 2024.

Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Coverage Rationale** • Added language to indicate combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary **Applicable Codes** • Added HCPCS codes A7021 and E0469 **Supporting Information** • Added *Clinical Evidence* section • Updated *References* section to reflect the most current information • Archived previous policy version CS054OH.B

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Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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