Clinical UM Guideline

Tennessee | Medicaid

Subject: Oscillation & Lung Expansion (OLE) Devices
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Description

This clinical guideline addresses airway clearance therapies particularly Oscillation & Lung Expansion (OLE) used to manage impaired secretion clearance associated with conditions such as asthma, COPD, cystic fibrosis, neuromuscular diseases, and other disorders affecting pulmonary function.

Note: For information regarding high frequency chest compression devices, please refer to:

- CG-DME-43 High Frequency Chest Compression Devices for Airway Clearance

Clinical Indications

Investigational and Not Medically Necessary:

Oscillation and lung expansion (OLE) devices are considered **investigational and not medically necessary** for all indications.

Discussion/General Information

Main and Rand (2023) performed a systematic review and meta-analysis assessing the efficacy and acceptability of conventional chest physiotherapy (CCPT) compared with alternative airway clearance techniques (ACTs) in individuals with cystic fibrosis (CF).

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Outcomes of interest included respiratory function, pulmonary exacerbations, exercise tolerance, treatment adherence, patient preference, and quality of life. Eligible studies were randomized or quasi-randomized controlled trials, including crossover trials, with intervention durations of at least seven days. Primary endpoints included pulmonary function testing and annual respiratory exacerbation frequency. Secondary endpoints included quality of life, adherence, exercise performance, additional pulmonary measures, oxygenation, nutritional status, mortality, mucus clearance, and sputum production outcomes. Results were categorized as short-term (7–20 days), medium-term (>20 days to 1 year), or long-term (>1 year).

Twenty-one studies involving 778 participants met inclusion criteria, including seven short-term, eight medium-term, and six long-term studies. Research was conducted primarily in the United States and Canada, with additional studies from Australia, the United Kingdom, Denmark, and Italy. Median study enrollment was 23 participants, with ages ranging from infancy to 45 years; most studies focused on pediatric and adolescent populations. Sixteen studies reported participant sex distribution, including 375 males and 296 females. Considerable heterogeneity existed among interventions regarding treatment duration, daily frequency, and comparison periods, limiting the feasibility of pooled analyses. Overall certainty of evidence was rated very low.

Nineteen studies evaluated pulmonary outcomes, specifically forced expiratory volume in one second (FEV1) and forced vital capacity (FVC). Across studies, no significant differences were observed between CCPT and alternative ACTs in change from baseline or decline in pulmonary function. Findings generally suggested comparable effectiveness between CCPT and alternative modalities, including positive expiratory pressure (PEP), extrapulmonary mechanical percussion, active cycle of breathing technique (ACBT), oscillatory PEP (O-PEP) devices, autogenic drainage (AD), and exercise-based interventions. Although isolated studies reported superiority of individual techniques, these findings were not consistently replicated, and pooled analyses generally demonstrated equivalent outcomes.

When comparing CCPT with PEP therapy, the authors found insufficient evidence to determine whether CCPT improved pulmonary function or reduced annual respiratory exacerbations. Narrative findings from several studies indicated favorable patient perceptions regarding the independence associated with PEP mask therapy. Comparisons between CCPT and extrapulmonary mechanical percussion also produced uncertain results, although high-frequency chest compression demonstrated a greater annual decline in FEF25-75 in some medium- and long-term studies.

In comparison with ACBT, evidence remained inconclusive regarding superiority of either intervention. One study reported a greater annual decline in FEF25-75 among participants using only the forced expiration technique component of ACBT. Another short-term study found

directed coughing to be comparable to CCPT for pulmonary outcomes. Hospitalization rates and inpatient days related to exacerbations did not differ significantly between groups. Evidence comparing CCPT with oscillatory PEP devices, including Flutter devices and intrapulmonary percussive ventilation, was similarly limited and of very low certainty. Available studies did not demonstrate meaningful differences in hospital admissions, duration of hospitalization, intravenous antibiotic use, or other secondary outcomes. Comparisons with autogenic drainage also failed to demonstrate clear superiority of CCPT, although one study reported more hospital admissions among participants receiving CCPT. Patient preference in one study favored autogenic drainage.

For exercise-based interventions, evidence remained uncertain. Reanalysis of one study suggested higher FEV1, FVC, and FEF25-75 values in the CCPT group; however, the original investigators reported no significant between-group differences after accounting for baseline variation. Overall, the authors concluded that current evidence is insufficient to establish whether CCPT provides greater benefit than alternative ACTs for pulmonary function, exacerbation frequency, adherence, quality of life, or exercise tolerance. While no clear respiratory advantage of CCPT was identified, the absence of demonstrated superiority likely reflects inadequate evidence rather than confirmed equivalence. Patient narratives frequently indicated preference for self-administered techniques. The review emphasized the need for larger, long-term, methodologically rigorous studies and concluded that no single ACT can currently be recommended over another.

Morrison and Milroy (2020) conducted a systematic review and meta-analysis evaluating oscillatory airway clearance devices, including oral and chest wall systems, in patients with cystic fibrosis. The review assessed whether oscillatory techniques improved mucociliary clearance and whether they were equivalent or superior to other physiotherapy modalities. Eligible studies included randomized and controlled clinical trials comparing oscillatory devices with alternative airway clearance approaches, excluding single-treatment interventions. Among 82 identified studies, 39 studies involving 1,114 participants satisfied inclusion criteria. Study durations ranged from less than one week to one year, and approximately half employed crossover designs. Considerable variation existed in intervention protocols and reported outcomes, limiting opportunities for quantitative synthesis. Most studies were considered at moderate to high risk of bias, and evidence quality ranged from low to very low according to GRADE criteria.

FEV1 was the most commonly assessed outcome. Although several studies demonstrated improvement from baseline among participants using oscillatory devices, few significant differences were observed when comparing oscillatory techniques with other airway clearance modalities. One study reported increased exacerbation frequency requiring antibiotics in participants using high-frequency chest wall oscillation compared with positive expiratory pressure therapy. Some secondary outcomes, such as sputum weight or volume, showed

small statistically significant differences; however, these findings were inconsistent and not uniformly favorable toward oscillatory devices.
Patient satisfaction was evaluated in 13 studies, but findings remained inconsistent. Some participants favored oscillatory devices, whereas others preferred traditional breathing techniques or previously established therapies. Due to limited evidence quality and inconsistent reporting, the authors concluded that no oscillatory device demonstrated clear superiority over alternative physiotherapy methods. They emphasized the need for adequately powered, long-term randomized controlled trials evaluating exacerbation frequency, treatment adherence, patient preference, and satisfaction, as improved adherence may ultimately influence pulmonary function and exercise tolerance. Additional research was also recommended to assess the effectiveness and cost implications of combining oscillatory devices with other airway clearance approaches.
Huynh et al. (2019) conducted a multicenter prospective study evaluating oscillation and lung expansion (OLE) therapy in reducing postoperative pulmonary complications (PPCs) among high-risk surgical patients. The intervention combined continuous high-frequency oscillation with continuous positive expiratory pressure. Stage I involved retrospective review of 210 patients undergoing thoracic, upper abdominal, or aortic surgery between December 2014 and April 2016. Stage II prospectively enrolled 209 patients between October 2016 and July 2017 who received OLE therapy in addition to standard respiratory care.
Compared with the retrospective cohort, patients in the prospective OLE group were older and had higher American Society of Anesthesiologists scores, indicating greater baseline risk. Despite this, OLE therapy was associated with a reduction in postoperative pulmonary complications from 22.9% to 15.8% after adjustment for confounding variables. OLE therapy also reduced ventilator duration and overall hospital length of stay. No significant differences were observed in ICU length of stay, pneumonia incidence, or mortality. The investigators concluded that aggressive OLE therapy may reduce postoperative pulmonary complications and healthcare resource utilization in high-risk surgical populations, although further prospective controlled trials are required to better establish safety and efficacy.

Background/Overview

Certain medical conditions, including asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), mucociliary disorders, neuromuscular diseases (NMD), and metabolic disorders, may impair normal airway clearance mechanisms.
Respiratory secretions are normally cleared through mucociliary function and effective coughing; however, these conditions may result in excessive secretion production,

increased secretion viscosity, or ineffective cough, leading to impaired clearance of airway secretions.

When airway secretions are not adequately cleared, mucus may accumulate within the bronchial tree, obstruct smaller airways, and impair normal gas exchange. Retained secretions may also promote bacterial colonization, increase the risk of chronic respiratory infections, and contribute to progressive decline in pulmonary function. Persistent mucus retention may further contribute to the development of bronchiectasis, a condition characterized by irreversible airway dilation and structural airway damage. Bronchiectasis may occur as a complication of chronic bronchitis within the spectrum of COPD and is also commonly associated with CF.

When coughing alone is insufficient to effectively clear airway secretions, additional airway clearance therapies may be medically necessary. Conventional chest physical therapy (CPT), including percussion and postural drainage techniques, has been used to facilitate secretion mobilization and improve respiratory function. These therapies are often taught to family members or caregivers for ongoing home use in individuals with chronic respiratory disease. However, conventional CPT may be labor-intensive and frequently requires daily assistance from a trained caregiver, which may negatively affect adherence to therapy.

To improve treatment adherence and promote greater patient independence, mechanical airway clearance devices have been developed. High-frequency chest wall compression (HFCWC), also referred to as high-frequency chest wall oscillation (HFCWO), is a mechanical form of CPT designed to promote mucociliary clearance and facilitate mobilization of pulmonary secretions. HFCWC/HFCWO devices typically consist of an inflatable vest connected to an air-pulse generator that rapidly inflates and deflates the vest, producing oscillatory chest wall compressions that may occur up to 20 times per second. These oscillations are intended to loosen and mobilize retained secretions, reduce mucus viscosity, and facilitate airway clearance.

Oscillation and Lung Expansion (OLE) therapy devices (for example, the Volara System) combine lung expansion, oscillation, and aerosol delivery therapies to assist with secretion mobilization and airway clearance. These devices are intended to support individuals with conditions associated with impaired secretion clearance and reduced pulmonary function.

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.

Definitions

Bronchiectasis: A disorder of major bronchi and bronchioles characterized by abnormal airway dilatation and destruction of walls with resulting inflammation, edema, ulceration, and distortion. When large, unusual spaces are formed inside the airways of the lungs, mucus secretions can collect in these spaces and be difficult to clear. This can often lead to more infections and further lung damage, most commonly from infection or recurrent inflammation. Bronchiectasis can also be acquired from a tumor, inhaling a foreign object, or from a congenital condition.
Bronchitis: An inflammation of the upper airways associated with cough and mucus. It can be caused by infections (infectious bronchitis) or inflammation (smoker's cough). Chronic bronchitis means that over the last 2 or more years, a person has been coughing up some mucus every day for at least 3 months out of the year.
Chest physiotherapy (CPT) (also known as chest physical therapy): The use of postural drainage, percussion, and vibration (PDPV) for airway clearance, which may also be referred to as percussion and postural drainage (P/PD). CPT is considered the standard of care of secretion clearance methods. This technique is time consuming, requires a skilled care provider and may be associated with discomfort, gastroesophageal reflux, and hypoxemia. The purpose of CPT is to improve mucociliary clearance and pulmonary function in order to reduce the risk of infection and lung damage.
Cystic fibrosis (CF): An autosomal recessive condition, the pulmonary manifestations of which include the production of excessive tenacious tracheobronchial mucus, leading to airway obstruction and secondary infection. This is the principal cause of morbidity and mortality associated with CF. Treatments focus on improving breathing and digestion, preventing and treating infections, and thinning mucus. Treatments include medicines, therapy to clear mucus out of the lungs, and in some cases, lung transplant.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time for service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are investigational and Not Medically Necessary: HCPCS

E0469 Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Hawkins, R., Weathers, S., Morton, R., O'Hagan, A. R., Stevens, E. L., Orangias, M., & Bickel, S. (2025). Impact of Home Use of Oscillation and Lung Expansion Therapy on Lung Function: A Case Series. American Journal of Respiratory and Critical Care Medicine, 211(Abstracts), A6511-A6511.
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6. Mushlin, N., Wanjala, M., Urrea, C., Koloms, K., & Becker, B. (2021). EVALUATION OF TRENDS IN PATIENT REPORTED OUTCOMES FOLLOWING INITIATION OF OSCILLATION AND LUNG EXPANSION THERAPY WITH THE VOLARA SYSTEM. *Chest*, *160*(4), A1871-A1872.
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Government Agency, Medical Society, and Other Authoritative Publications:

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g. Morrison **L,** Milroy S. Oscillating devices for airway clearance in people with cystic fibrosis. Cochrane Database of Syst Rev 2020; (4):CD006842.Osadnik CR, McDonald CF, Jones AP, Holland AE. Airway clearance techniques for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2012;(3):CD008328.
h. Strickland SL, Rubin BK, Drescher GS, et al. American Association for Respiratory Care (AARC) clinical practice guideline: Effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. Respir Care. 2013; 58(12):2187-2193.
i. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J. 2017; 50(3):1700629.
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k. Yankaskas JR, Marshall BC, Sufian B, et al. Cystic fibrosis adult care: consensus conference report. Chest. 2004; 125(1 Suppl):1S-39S.

Websites for Additional Information

1. Cystic Fibrosis Foundation. Available at: **www.cff.org.**

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OLE
Percussionaire Device

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	06/09/2025	TN Medical Advisory Committee review.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The members' contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.