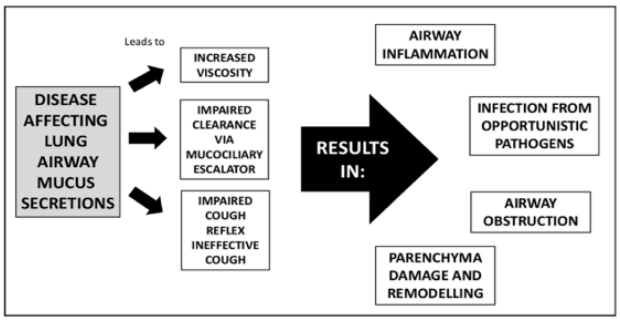
BIWAZE® CLEAR CLINICAL VALUE DOSSIER

EXECUTIVE SUMMARY

BIWAZE® CLEAR is an advanced airway clearance system that delivers Oscillating Lung Expansion (OLE) therapy to remove retained secretions in the lower, distal airways and to expand narrowed or collapsed airways. OLE (also called Oscillating and Pulmonary Expansion) therapy has been clinically proven to reduce pulmonary complications in individuals with impaired respiratory function.[7,21]

BIWAZE® CLEAR provides a breathing treatment of OLE therapy delivered via a patient interface of either a mouthpiece, face mask, or tracheostomy adapter. OLE therapy provides lung expansion using a set expiratory pressure to increase forced residual capacity, which can increase ventilation and open closed or blocked airways.[1] The therapy also provides high-frequency oscillation where the system will vary the airflow to a set peak pressure to break up and thin mucus deep in the lungs. Medicated aerosol can be delivered to help calm inflamed airways and thin the mucus with the Aerogen® Solo nebulizer throughout the therapy.

Excessive mucus buildup in the airways is linked to chronic conditions such as COPD, bronchiectasis, cystic fibrosis, and neuromuscular diseases. When mucus becomes more viscous, it impairs the mucociliary escalator, reducing its ability to clear the airways. This, combined with ineffective expectoration, can lead to inflammation, infection, airway obstruction, and damage to lung tissue.



Respiratory therapists employ various airway clearance techniques (ACTs) as a critical part of treatment to help clear thick, adhered mucus, reduce the risk of lung infections, and improve lung function.[22] While many ACTs are available, the most commonly prescribed for home care are lung expansion and high-frequency chest wall oscillation.[11,13,17,18]

The BIWAZE® CLEAR system integrates three proven airway clearance therapies or functions into one innovative solution: lung expansion, high-frequency oscillation, and nebulization. BIWAZE® CLEAR delivers deep airway clearance through:

- Mechanically driven lung expansion
- Internal high-frequency oscillation
- Advanced vibrating mesh nebulization

The OLE therapy delivered with the BIWAZE® CLEAR system has several advantages over the existing lung expansion and high-frequency chest wall oscillation therapies prescribed today, including a reduction in therapy time, greater therapy efficiency, and improved patient comfort.[23]

BURDEN OF ILLNESS

Chronic conditions present significant challenges in respiratory health, often requiring specialized, multidisciplinary care. Understanding the unique aspects and prevalence is crucial for effective management and resource allocation.

Chronic Obstructive Pulmonary Disease (COPD) is a progressive lung disease that restricts airflow, making breathing increasingly difficult over time. It primarily includes two main conditions: chronic bronchitis (which causes long-term inflammation and mucus production) and emphysema (which damages the air sacs in the lungs). The condition is typically caused by long-term exposure to irritating gases or particulate matter, most commonly from cigarette smoke. Those with COPD often experience symptoms like shortness of breath, wheezing, and chronic cough.[29]

Bronchiectasis involves the permanent widening and thickening of the bronchi due to chronic inflammation or infection, resulting in abnormal mucus accumulation. Over time, this accumulation can make the lungs more susceptible to infections, worsening breathing issues and potentially leading to irreversible lung damage. Causes of bronchiectasis range from severe lung infections to genetic conditions that weaken lung structure, such as cystic fibrosis.[30]

Cystic Fibrosis (CF) is a genetic condition caused by mutations in the CFTR gene, leading to thick and sticky mucus that clogs the lungs and pancreas. This can cause severe respiratory issues and malnutrition due to digestive malabsorption. Symptoms commonly include persistent lung infections, difficulty breathing, and poor growth in children.[31]

Neuromuscular diseases encompass a range of disorders, including muscular dystrophy, amyotrophic lateral sclerosis (ALS), and myasthenia gravis, that impair the nerves controlling voluntary muscles and lead to muscle weakness, wasting, and impaired movement. They can also affect respiratory function, making it hard to breathe independently as the disease progresses.[32] Each diagnosis has unique challenges and management strategies, often involving multidisciplinary care to support respiratory and overall health.

Prevalence of these conditions:

- Over 17 million American adults are currently diagnosed with COPD.[33]
- The incidence of bronchiectasis is estimated to be around 139 cases per 100,000 adults in the U.S., translating to several hundred thousand cases nationwide. Rates of bronchiectasis have risen in recent years, especially in older adults and those with a history of respiratory conditions.[34,35]
- Cystic fibrosis affects roughly 30,000 people in the United States, with approximately 1,000 new cases diagnosed annually. CF is predominantly diagnosed in childhood, though improvements in treatment have increased life expectancy, allowing many patients to live well into adulthood.[36]
- Neuromuscular diseases impact several hundred thousand individuals in the U.S., though exact figures depend on specific conditions within this category.[32]

The typical costs associated with treating these diseases vary significantly based on severity, complications, and the specific interventions required.

PRODUCT INFORMATION

The BIWAZE® CLEAR System helps patients loosen and mobilize secretions while also treating and preventing atelectasis through lung expansion and high-frequency oscillation therapies. Its oscillating lung expansion therapy is designed to clear airway obstructions caused by secretions in the lower airways, prevent respiratory infections, re-expand collapsed lung areas, improve gas exchange, and reduce inflammation.

The BIWAZE® CLEAR system received FDA 510(k) clearance in 2022 for the loosening and mobilization of secretions, lung expansion therapy, and the treatment and prevention of pulmonary atelectasis. It can also provide supplemental oxygen when connected to an oxygen supply. BIWAZE® CLEAR is designed for use in treating respiratory conditions such as COPD, bronchiectasis, cystic fibrosis, and neuromuscular diseases and conditions like muscular dystrophy, spinal muscular atrophy, amyotrophic lateral sclerosis, spinal cord injury, and cerebral palsy. The system can deliver therapy through different patient interfaces like a mouthpiece, trach adapter, or face mask (available in various sizes to accommodate different patient face shapes).

The BIWAZE® CLEAR System delivers OLE therapy in just 10 minutes through a combination of the following functions in one integrated respiratory solution:

- **Positive Expiratory Pressure (PEP):** The system delivers a programmed positive pressure, which the patient exhales against to open and expand the patient's airways. The device provides continuous positive pressure to the patient's airway, opening regions of the lung that are otherwise closed off during tidal volume breathing. Additionally, PEP helps mobilize peripheral lung secretions into the larger airways and contributes to resolving atelectasis by preventing airway collapse during expiration. The Aerogen® Solo can be configured to run during PEP therapy to help move the aerosol throughout the airways.
- **High-Frequency Oscillation:** The system oscillates the airways internally with pulses of positive pressure. These pulsations shear or break down the mucus, loosen it from the walls of the peripheral airways, and use the airflow to mobilize the mucus toward the central airways, as a form of chest physiotherapy. The Aerogen® Solo can be configured to run during oscillation therapy to help move the aerosol throughout the airways.
- **Nebulizer:** The system powers the Aerogen® Solo vibrating mesh nebulizer to deliver medicated aerosol concurrently with PEP and OSC for treatment efficiency or used as a stand-alone therapy.*

Note: The supplemental oxygen capability supports the delivery of oxygen during OLE therapy for patients who are dependent on oxygen.

The BIWAZE® CLEAR System utilizes a platform from which both PEP and OSC can be administered during alternating periods in a single treatment session. Treatments are provided in cycles with alternating intervals of 2.5 minutes of PEP to open the airways and 2.5 minutes of OSC to create airflow within the lungs to move retained secretions. Caregivers have the option of adjusting the duration of each interval based on the physician's orders.

KEY FEATURES

BIWAZE® CLEAR innovates oscillating lung expansion (OLE) therapy with an advanced design that:

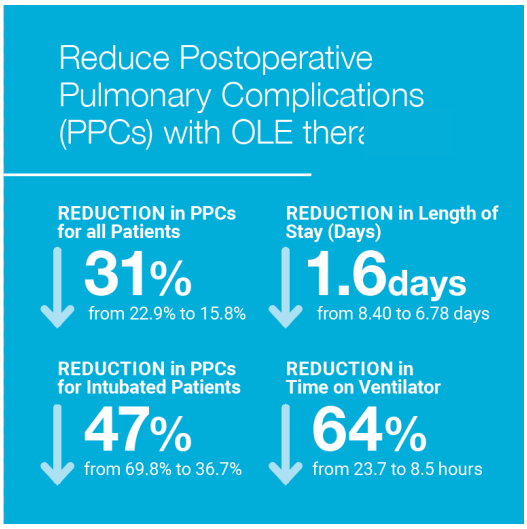
- DELIVERS unmatched aerosol efficiency, deeper into the lungs.[9]
- FEATURES a closed breathing circuit with Aerogen® Solo and a built-in controller.
- INCLUDES a lithium-ion battery with every light-weight system.
- SIMPLIFIES therapy setup and delivery with an intuitive touchscreen.

The BIWAZE® CLEAR system delivers therapy with an electronically controlled dual-blower system. There is no venturi, no open exhalation port, and no jet nebulizer. The system has a dual-lumen breathing circuit and a vibrating mesh nebulizer, so the entire breathing circuit is closed. As a result, the patient's exhaled breath is filtered by a coaxial bacterial-viral filter before entering the room air, providing a safer environment without fugitive aerosols.[9]

The BIWAZE® CLEAR system is contraindicated for untreated tension pneumothorax. Patients with a history of pneumothorax, pulmonary air leak, recent pneumonectomy, pulmonary hemorrhage, myocardial infarction, and vomiting should be carefully evaluated before a decision is made to use the therapy.

CLINICAL EVIDENCE

The clinical evidence supporting OLE therapy is substantial. Several studies have evaluated feasibility and safety. However, the primary clinical evidence for safety and efficacy was obtained in the study by Huynh et al. titled “Efficacy of Oscillation and Lung Expansion in Reducing Pulmonary Complication” (2019). The study investigated the clinical benefits of Oscillation and Lung Expansion (OLE) therapy in reducing postoperative pulmonary complications (PPCs) Overall, the study's findings suggest that OLE therapy not only improves patient outcomes but also has the potential to significantly reduce healthcare costs associated with PPCs, making it an economically beneficial approach for hospitals and payers alike.



Background: Postoperative pulmonary complications (PPCs) cause high morbidity and mortality. Targeted treatment for patients at risk for PPCs can improve outcomes. This multicenter prospective trial examined the impact of oscillation and lung expansion (OLE) therapy using continuous high-frequency oscillation and continuous positive expiratory pressure on PPCs in high-risk patients.

Methods: In stage I, CPT and ICD codes were queried for patients (n = 210) undergoing thoracic, upper abdominal, or aortic open procedures at three institutions from December 2014 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 PPC rates (prolonged ventilation, high-level respiratory support, pneumonia, ICU readmission) were compared. We also compared ICU length of stay (LOS), hospital LOS, and mortality using t-tests and analysis of covariance. Data are mean ± SD.

Results: 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.

Conclusions: Aggressive treatment with OLE reduces PPCs and resource use in high-risk surgical patients.

Results of the study were published in the high-impact journal of the Journal of the America College of Surgeons, 2019 Nov; 229(5): 458-466e1.

ADDITIONAL EVIDENCE

The complex nature of respiratory illness demands both clinical assessment and a combination of therapies to support lung health. First-line treatments typically involve nebulizer or aerosol therapy, which requires proper breathing techniques to deliver medication to the lower airways. Second-line treatments often include lung expansion therapy, which relies on effort-dependent techniques to increase lung volume. While national medical societies recommend lung expansion therapy,[12,13,17] research shows that these techniques may be less effective postoperatively due to inadequate technique, fatigue, or pain, potentially resulting in suboptimal lung expansion and higher rates of pulmonary complications, hospitalizations, or increased medication use.[19] The third-line treatment for airway clearance is high-frequency chest wall oscillation or some form of chest physiotherapy technique to help break up mucus deep in the lungs,[11,17,18,19] but not all patients can tolerate compression to their thorax nor do they spend the time performing the therapy properly.[1,2,8,13,17]

Greater therapy efficiency with consistency and control

Mechanical lung expansion versus patient effort and technique dependent. Research shows that patients often underperform with incentive spirometers or other patient-driven lung expansion methods due to inadequate technique, fatigue, or pain postoperatively, leading to suboptimal lung expansion and potentially higher rates of complications pulmonary exacerbations like lung infection leading to

hospitalization or increased medication use. Mechanically delivered lung expansion therapies are especially beneficial for patients at high risk of pulmonary complications, such as those with chronic obstructive pulmonary disease (COPD), cystic fibrosis, bronchiectasis, neuromuscular disorders, or those who have recently undergone surgery. These patients often have reduced capacity for deep breathing due to pain or illness and may struggle to use traditional devices effectively.[18]

Improved patient comfort with internal vs. external high-frequency oscillations

BIWAZE® CLEAR delivers targeted oscillations directly to the airways through a mouthpiece, trach adapter, or mask, focusing on the lungs to facilitate mucus clearance with minimal impact on the rest of the body. This results in a localized, less physically demanding therapy for patients. In contrast, external vest therapy applies oscillations via a garment that rapidly inflates and deflates, creating a shaking sensation across the chest. This external compression can be uncomfortable for many patients due to its broader, more forceful action.[1,2,8,13,17]

Internal high-frequency oscillations, by comparison, offer a gentler, more comfortable experience. Without the need for restrictive garments or intense chest vibrations, this therapy reduces skin irritation and physical discomfort, particularly for geriatric patients with osteoporosis. This makes it a more patient-friendly option, especially for those sensitive to the demands of external therapies.

Reducing therapy time

The BIWAZE® CLEAR system expands and clears the airways through a combination of airway clearance therapies in just 10 minutes, which provides time savings when compared to the standard HFCWO therapy time of 30 minutes.

ECONOMIC IMPACT

Based on the results of the multicenter prospective trial, which examined the impact of oscillation and lung expansion (OLE) therapy, using continuous high-frequency oscillation and continuous positive expiratory pressure to reduce postoperative pulmonary complications in high-risk patients[7], a cost-effectiveness modeling study was performed utilizing data from other studies and statistics from Society of Critical Care Medicine.

	Potential Cost Savings	Before OLE	With OLE	Cost savings from reduced time on ventilator
Reduced time on ventilator[7]	Incremental cost of mech. Ventilation in ICU pt/day[26]	$1,522	$1,522	
	Average number of ICU days[24]	4 days	1.44	
	Average cost of ICU stays	$6,088	$2,192	$3,896

	Potential Cost Savings	Before OLE	With OLE	Cost savings from reduced time in ICU
Reduced number of days in the ICU[24]	Average ICU cost per day[25]	$4,300	$4,300	
	Average number of ICU days[24]	1.45 days	0.73 days	
	Average cost of ICU stays	$6,235	$3,118	$3,118

Reduced in hospital LOS[7]	Potential Cost Savings	Before OLE	With OLE	Cost savings from reduced hospital LOS
	Average cost of hospital per day[28]	$3,000	$3,000	
	Average hospital LOS[7]	6 days	4.4 days	
	Average cost of hospital stays	$18,000	$13,200	$4,800

The total potential cost savings of implementing OLE therapy is $11,814 for one patient's hospital stay.

CODING AND COVERAGE

As of October 1, 2024, the Centers for Medicare and Medicaid Services (CMS) released a final HCPCS coding and payment decision to create two new codes for a lung expansion airway clearance, continuous high-frequency oscillation, and nebulization device.

HCPCS Code	Description	Payment
E0469	Lung expansion airway clearance, continuous high-frequency oscillation, and nebulization device	The Medicare payment amount used a fee schedule for comparable items in accordance with regulations at 42 CFR 414.238. The final payment determination for HCPCS Level II code E0469 is calculated using the following formula: E0469= E0483 + ((E0482/2) *10/60) + (E0570*10/60). The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0469 will be approximately $1,505.16 for months 1 through 3 and approximately $1,128.90 for months 4 through 13.
A7021	Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation and nebulization device. The disposable supply kit includes a handset, nebulizer, breathing tube, biofilter and patient interface.	The final payment determination for HCPCS Level II code A7021 is calculated using the following formula: A7021 = A7030 + A7003 + A7004 + A7037 + A7039. The average 2024 non-rural purchase fee schedule amount for new code A7021 will be approximately $137.34.

HCPCS code E0469 has been assigned to the Durable Medical Equipment (DME) benefit category, which is defined in Medicare regulations at Title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all the following conditions:

a. It can withstand repeated use.
b. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
c. It is primarily and customarily used to serve a medical purpose.
d. Generally, it is not useful to an individual in the absence of an illness or injury.
e. It is appropriate for use in the home.

HCPCS code A7021 is classified as inexpensive and other routinely purchased items. They are necessary for the effective use of durable medical equipment, and payment will be made on a purchase basis.

CONCLUSION

The BIWAZE® CLEAR is a proven, safe, and efficient airway clearance solution that addresses significant unmet needs in respiratory care, particularly for high-risk patients who face challenges with traditional, effort-dependent lung expansion and high-frequency chest wall oscillation (HFCWO) therapies. By providing consistent lung expansion and airway clearance through internal high-frequency oscillations, BIWAZE® CLEAR offers a dependable, automated approach designed to enhance patient adherence and improve clinical outcomes.

We respectfully request that you expand your current medical policy to include coverage for the code and payment established by the Centers for Medicare & Medicaid Services (CMS). This expansion would apply to patients currently covered under the Local Coverage Determination (LCD) L33785 for E0483, L33795 for E0482, as well as L33370 for E0570. These codes, deemed comparable by CMS, reflect the three integrated functions of OLE therapy delivered by the BIWAZE® CLEAR system.

* Currently FDA cleared for saline solution only

For further information about this product or service, visit our webpage:
https://abmrc.com or call customer support: 1-877-ABMRC01 (877-226-7201)

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