

INTERNATIONAL BIOPHYSICS CORPORATION

Over a quarter of a century legacy
of unwavering commitment to
creating innovative and disruptive
medical devices and technologies
that improve treatment therapies and
patient outcomes.

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IS IT MORE THAN COPD?

LEARN HOW AIRWAY CLEARANCE
THERAPY IS A PREVENTATIVE
TREATMENT OPTION THAT CAN HELP
AT-RISK PULMONARY PATIENTS

PREVENTATIVE PULMONARY HYGIENE

Now is the time to promote pulmonary and bronchial hygiene for at-risk pulmonary patients to be in the best health possible.

Airway Clearance Therapy is a cornerstone therapy for the prevention and treatment of pulmonary disease and neurorespiratory dysfunction¹. The goal of Airway Clearance Therapy is to provide a preventative treatment option for at-risk pulmonary patients that results in reduced, recurring hospitalizations and better overall health. ^{2,3}

Who is the "At-Risk" Respiratory Patient?

- Pulmonary Compromised
- History of Pneumonia
- Chronic Respiratory Conditions
- COPD
- Bronchitis, Emphysema
- Chronic Asthma
- Bronchiectasis
- Disorders of The Diaphragm

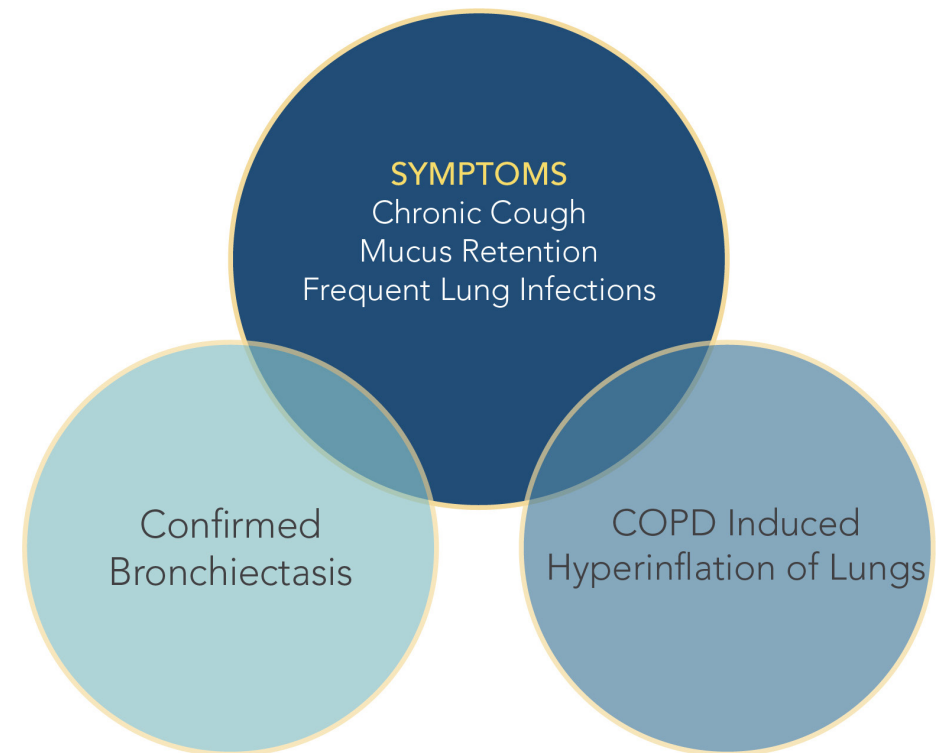


THE SYMPTOM OVERLAP

The typical symptoms for chronic airway diseases are similar and can overlap, which can make it difficult for appropriate diagnosis.

Chronic airway diseases share common symptoms but are characterized by differences in lung function, acute exacerbations and mortality.⁴

It is important for an accurate diagnosis as to attain the best care plan as soon as possible, which can lead to improved treatment, intervention, prognosis and quality of life.⁵



CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Chronic Obstructive Pulmonary Disease (COPD) is an umbrella term to describe a group of chronic, progressive lung diseases that affect the lungs and cause reduced airflow and breathing problems.

Symptoms of COPD include:

- Chronic cough
- Shortness of breath (dyspnea)
- Wheezing
- Frequent respiratory infections / pneumonias
- Producing excessive mucus / mucus plugging



With COPD, the airways in your lungs become inflamed and thicken, and the tissue where oxygen is exchanged is destroyed. The flow of air in and out of the lungs decreases and airways produce more mucus than usual, which can clog them.



Mucus hypersecretion in all COPD patients affects lung function, health-related quality of life, COPD exacerbations, hospitalizations, and mortality.⁶

BRONCHIECTASIS OR COPD?

Bronchiectasis is a chronic condition that occurs when the walls of the airways thicken as a result of chronic inflammation and/or chest infections.

Bronchiectasis can be tricky because it often presents like COPD, but won't respond to COPD therapy. A considerable portion of COPD patients should have a more accurate diagnosis of bronchiectasis or possibly an overlap combination of bronchiectasis with asthma or COPD.⁵

Symptoms both respiratory diseases have:

- Chronic cough
- Shortness of breath
- Daily mucus production / mucus plugging
- Frequent exacerbations
- Airflow obstruction
- Frequent lung infections / pneumonias

Studies show it's much more prevalent than what's being diagnosed.

42% OF COPD PATIENTS MAY HAVE BRONCHIECTASIS⁷ WITH 70,000 NEW PATIENTS EACH YEAR⁸



Approximately 5 Million COPD Patients have Bronchiectasis

Diagnosis of bronchiectasis in COPD patients allows for proper treatment of underlying infection and inflammation and allows for needed airway clearance therapy.

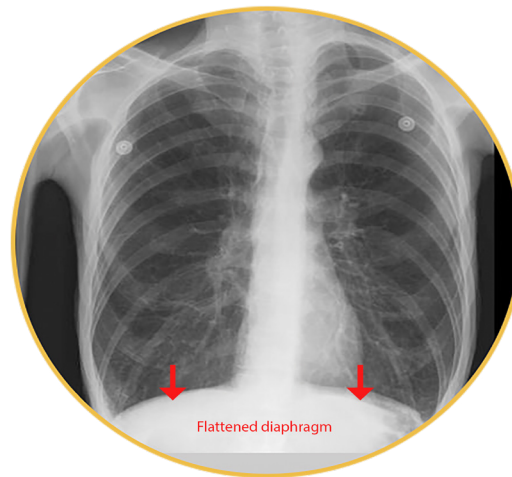
HYPERINFLATION OF THE LUNGS IN COPD PATIENTS

BENEFITS OF AIRWAY CLEARANCE THERAPY

COPD patients often develop hyperinflation of the lungs, which can lead to a flattened diaphragm.⁹ Hyperinflation of the lungs occurs when an increase in lung volume prevents efficient airflow in the body.

Patients with COPD often have some degree of hyperinflation of the lungs which can push on the diaphragm, causing it to flatten, lose tone, and stop working properly.

A chest X-Ray image of COPD patients may reveal enlarged lungs and a flattened diaphragm.



Diaphragmatic weakness or paralysis may be seen in diseases that cause lung hyperinflation.¹⁰

Symptoms of a flattened diaphragm include:

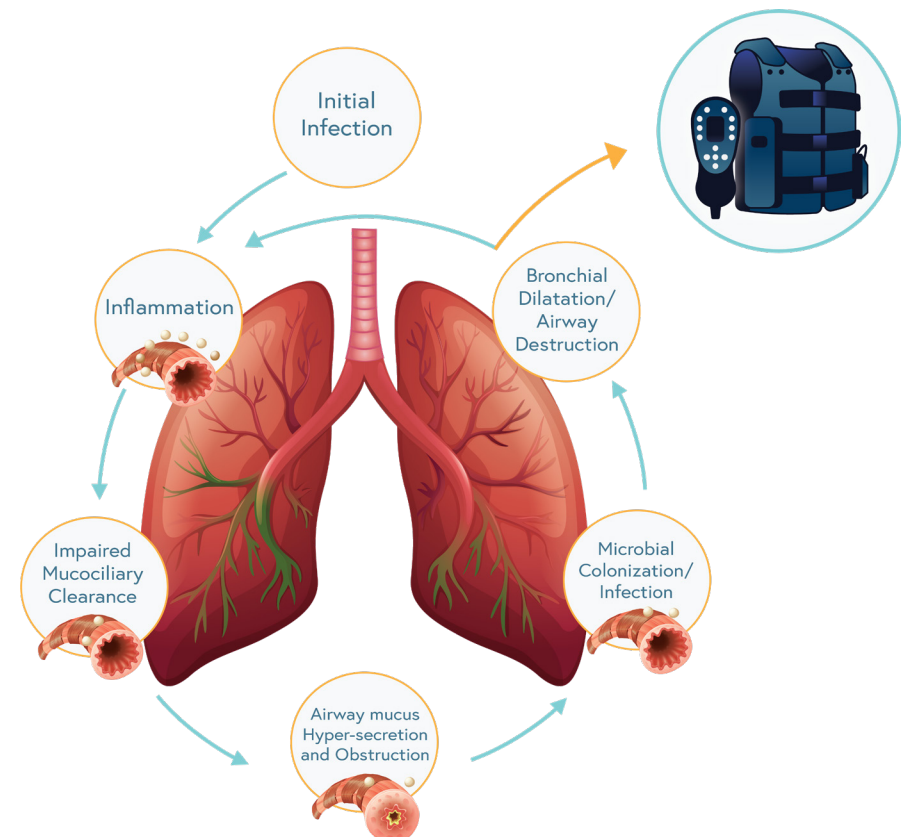
- Coughing or wheezing
- Production of excess mucus
- Difficulty breathing
- Continuous efforts to catch their breath
- Tightness in the chest

The flattening causes a disorder of the diaphragm - a relaxation or paralysis - which can lead to difficulty with coughing and clearing secretions, mucus plugging and recurring pulmonary infections.

Effective mucus clearance is essential for pulmonary hygiene and airway disease is often a consequence of poor clearance.

Airway obstruction and damage to the airways may result from recurring mucus build up, infection, and inflammation, also known as the vicious cycle of bronchiectasis.

Airway clearance therapy has been a cornerstone of therapy for the prevention and treatment of pulmonary diseases, aimed at minimizing the devastating effects of airway obstruction, infection, and inflammation due to mucus buildup in the airways.



AFFLOVEST® MOBILE MECHANICAL HFCWO THERAPY

MEDICARE ICD-10 CODES FOR AFFLOVEST

AffloVest® is a proven high frequency chest wall oscillation (HFCWO) therapy designed to provide patients the freedom and mobility to customize and enhance airway clearance therapy, help mobilize lung secretions, and promote treatment adherence for patients with bronchiectasis, disorders of the diaphragm or other respiratory diseases.

TAILORED THERAPY



Designed to mimic the gold standard Chest Physical Therapy, AffloVest's eight anatomically positioned oscillating motors target all lobes of the lungs, front and back, to loosen, thin and mobilize lung secretions.

MOBILITY



The battery-powered AffloVest is designed to increase therapy adherence through **mobility during use**, which can provide more consistent therapy compliance and an improved quality of life.

COMFORTABLE DESIGN



With 7 sizes from XXS-XXL, the ergonomic fit of the AffloVest can accommodate different patient needs for tailored therapy that fits young children and adults.

UNIQUE FEATURES INCLUDE:

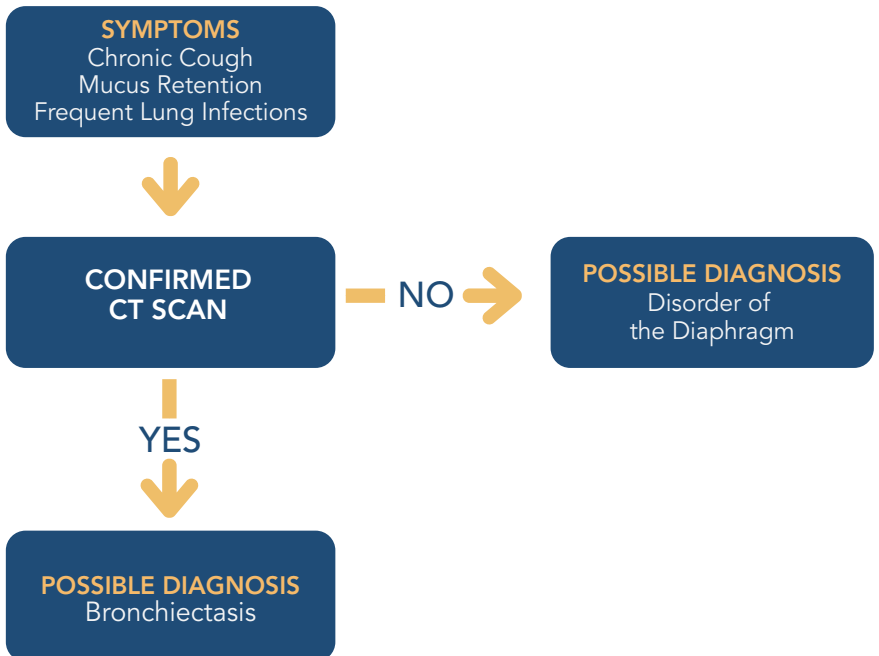
- Anatomically targeted therapy
- Fully mobile during use
- Digital, programmable controller
- 3 modes of oscillation treatment
- 3 adjustable intensity levels
- Quiet during operation
- Designed to increase patient adherence
- Compliance monitoring



COPD patients can be prescribed AffloVest Mobile HFCWO therapy with the diagnosis of bronchiectasis or disorder of the diaphragm.

Medicare approved diagnosis for AffloVest or HFCWO equipment:

- Bronchiectasis with Acute Lower Respiratory Infection (J47.0)
- Bronchiectasis with (Acute) Exacerbation (J47.1)
- Congenital Bronchiectasis (Q33.4)
- Bronchiectasis, uncomplicated (J47.9)
- Disorders of the Diaphragm (J98.6)



The AffloVest has received the FDA's 510k clearance for U.S. market availability, and is approved for Medicare, Medicaid, and private health insurance reimbursement under the Healthcare Common Procedure Coding System (HCPCS) code E0483 – High Frequency Chest Wall Oscillation. The AffloVest is also available through the U.S. Department of Veterans Affairs/Tricare. Patients must qualify to meet insurance eligibility requirements.

AFFLOVEST® REIMBURSEMENT CONSIDERATIONS

MEDICARE REQUIREMENTS FOR BRONCHIECTASIS:



Daily productive (mucus) cough for at least 6 continuous months

OR



Frequent (i.e., more than 2/year) exacerbations/chest infections requiring antibiotic therapy

AND



Well-documented failure of other standard treatments (flutter valve, percussion, postural drainage, breathing techniques) to adequately mobilize retained secretions.

AND



Diagnosis confirmed via a CT scan

MEDICARE REQUIREMENTS FOR DISORDERS OF THE DIAPHRAGM AND OTHER CONDITIONS:



Diagnosis

AND



Chart Notes to support the diagnosis

AND



Well-documented failure of other standard treatments (flutter valve, percussion, postural drainage, breathing techniques) to adequately mobilize retained secretions.

Refer to the full list of ICD-10 codes on the Medicare LCD.

AFFLOVEST® REIMBURSEMENT CONSIDERATIONS

Well-documented failure of other treatments to adequately mobilize retained secretions/airway clearance

To ensure coverage of HFCWO therapy, thorough chart notes indicating that other treatments aimed at mobilizing secretions have been tried and failed or thorough documentation of why other treatments would not be sufficient or are not an option for a specific patient.

COMMON REASON AIRWAY CLEARANCE TREATMENTS FAILS

- Did not mobilize secretions
- Unable to tolerate positioning (CPT)
- Insufficient expiratory force
- Physical limitations of patient or caregiver
- No caregiver available
- Cognitive level
- Severe arthritis/osteoporosis

COMMON AIRWAY CLEARANCE TREATMENT TRIED, FAILED OR INAPPROPRIATE - EXAMPLES

- Patient tried Chest Physical Therapy (CPT) but was unable to tolerate treatment or has no caregiver available to perform treatment.
- Patient used Flutter/Acapella device but it did not effectively mobilize secretions.
- Patient has insufficient expiratory force to perform Huff Cough effectively to mobilize secretions.

Information provided can help determine the correct billing and coding procedures and gives suggestions to meet Medicare, Medicaid and private insurance requirements. This information is based on clinical references and certain billing requirements and is designed to help make your own determination of patient eligibility.