Medicare Coverage Criteria for inCourage® Airway Clearance Therapy (E0483)

As part of our service to your patients, RespirTech submits all required documentation to your patient’s insurance plans for reimbursement of the inCourage® System. We will work with you to obtain the required documentation.

Medicare Coverage Criteria and Documentation Requirements

The following table summarizes the covered diagnosis requirements from Medicare.

<table>
<thead>
<tr>
<th>Medical Record Documentation Requirements</th>
<th>Bronchiectasis</th>
<th>Cystic Fibrosis</th>
<th>ALS and Other Anterior Horn Cell Disease</th>
<th>Muscular Dystrophy, Hereditary</th>
<th>Paralysis of the Diaphragm</th>
<th>Myotonic Disorders</th>
<th>Multiple Sclerosis</th>
<th>Other Myopathies</th>
<th>Acid Maltase Deficiency</th>
<th>Paralysis of the Diaphragm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed and dated written order prior to delivery</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Records supporting diagnosis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Face-to-face encounter within last 6 months</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Tried and Failed Alternative Therapies (See A)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Daily productive cough for at least 6 continuous months or Exacerbation requiring antibiotic therapy at least 3 times within the last year</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CT Scan confirming diagnosis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Continued Use and Medical Need (See B)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

For further information on use of inCourage Airway Clearance Therapy (E0483) and CoughAssist Device (E0482), see C on next page.

A. “TRIED AND FAILED” OR CONSIDERED ALTERNATIVE THERAPIES

Considerations for “tried and failed” documentation in the patient’s progress notes:

1. Which Airway Clearance Therapies have been “tried and failed” for the patient? (List of examples):
   - CPT (Manual or Percussor)
   - PEP (acapella®/Flutter®)
   - CoughAssist
   - Autogenic Drainage
   - “Huff Cough”

2. Include all reasons why the above therapy failed, is contraindicated, or is inappropriate for the patient. (List of examples):
   - Artificial Airway
   - Did Not Mobilize Secretions
   - No Skilled Caregiver Available
   - Spasticity/Contractures
   - Arthritis/Osteoporosis
   - Feeding Tube
   - Resistance to Therapy
   - Too Fragile for Percussion
   - Aspiration Risk/GERD
   - Insufficient Expiratory Force
   - Scoliosis/Rod Placement
   - Unable to Form Mouth Seal

Flutter® is a registered trademark of VarioRaw Percutive S. àr.l., a subsidiary of Aptalis Pharma US, Inc. acapella® is a registered trademark of Smiths Medical.
B. CONTINUED USE AND MEDICAL NEED

Add the inCourage System to the patient’s list of current medications so the therapy can be reviewed at each visit to document continued use and medical need to the patient.

C. COUGHASSIST DOCUMENTATION GUIDELINES

inCourage Airway Clearance Therapy and a CoughAssist device can provide complementary airway clearance therapy. Due to the different mechanisms of action, the inCourage System should be prescribed first to effectively move secretions from the periphery to the central airways where they can be expectorated. With diseases where the patient’s ability to cough is impaired, the CoughAssist device would then be an appropriate complement to inCourage Therapy.

Medicare and any payers following Medicare coverage criteria will not reimburse for both inCourage Therapy and a CoughAssist device. RespirTech will coordinate the appeals process in cases where Medicare and other payers following Medicare criteria deny coverage for utilization of both therapies.

Private Payer Coverage
Private payers often follow Medicare’s coverage policies and may also require prior authorization as a condition of coverage. Some may require specific documentation or may not cover all of the diagnoses in Medicare’s coverage guidelines. Most will also require that alternative, standard airway clearance therapies have been tried and failed prior to approving inCourage Therapy for coverage.

Medicaid Coverage
State and local government agencies operate Medicaid and other programs for low-income and disabled individuals and their families. While these programs tend to track Medicare’s policies on coverage, they may not utilize the same coverage guidelines. Thus, coverage and documentation requirements for inCourage Therapy by government-run programs in the state and local level can vary considerably and will require specific benefit determination.

What is Considered Medical Documentation
It is important to note all coverage criteria outlined on this form must be contained in the patient’s medical record in order to maintain compliance with Medicare and other insurance programs. A prescription is not considered a part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

Questions? We’re Here to Help
Contact RespirTech Customer Care
Toll Free: 800.793.1261

This educational information offers general coverage, coding and payment information for procedures associated with use of high frequency chest wall oscillation (HFCWO). This is not legal guidance, nor is it advice about how to code, complete, or submit any particular claim for payment. It is always the provider’s responsibility to determine coverage and submit appropriate codes and charges for services rendered. This is based on the medical necessity of the services and supplies provided, the requirements of insurance carriers and any other third-party payers, and any local, state or federal laws that apply to the products and services rendered. Given the rapid and constant change in public and private reimbursement, we cannot guarantee the accuracy or timeliness of this information.