## REQUIRED DOCUMENTATION

- **5 Element Order** obtained prior to delivery for the HCPCS code E0194
  - 5 Element order (5EO) contains:
    - Beneficiary’s name
    - Prescribing physician/practitioner’s NPI
    - A description of the item of DME ordered - the description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - Signature of the prescribing physician/practitioner
    - Order date
  - The 5EO must be completed within six (6) months after the required face-to-face examination.
  - The date of the written order shall be on or before the date of delivery.
  - Any changes or corrections have been initialed/signed and dated by the ordering practitioner.

### Delivery Documentation

<table>
<thead>
<tr>
<th>Direct Delivery</th>
<th>Shipped/Mail Order Tracking Slip</th>
<th>Shipped/Mail Order Return Post-Paid Delivery Invoice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiary’s name</td>
<td>Shipping invoice</td>
<td>Shipping invoice</td>
</tr>
<tr>
<td>Delivery address</td>
<td>Beneficiary's name</td>
<td>Beneficiary’s name</td>
</tr>
<tr>
<td>Quantity delivered</td>
<td>Delivery address</td>
<td>Delivery address</td>
</tr>
<tr>
<td>A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.</td>
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</tr>
<tr>
<td>Delivery date</td>
<td>Quantity shipped</td>
<td>Quantity shipped</td>
</tr>
<tr>
<td>Signature of person accepting delivery</td>
<td>Tracking slip</td>
<td>Date shipped</td>
</tr>
<tr>
<td>Relationship to beneficiary</td>
<td>References each individual package</td>
<td>Date delivered</td>
</tr>
</tbody>
</table>

**NOTE:** If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.

2. Suppliers may use the date of delivery as the DOS on the claim.
□ Medical Records
□ The medical record includes a face-to-face examination by the treating physician that meets the following requirements:
  □ The examination occurred within 6 months prior to the date of the written order that was obtained prior to delivery; and
  □ The examination documents that the beneficiary was evaluated and/or treated for a condition that supports the need for an air-fluidized bed.
□ The medical record supports that the beneficiary meets all of the following criteria:
  □ The beneficiary has a stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure ulcer.
  □ The beneficiary is bedridden or chair bound as a result of severely limited mobility.
  □ In the absence of an air-fluidized bed, the beneficiary would require institutionalization.
  □ The air-fluidized bed is ordered in writing by the beneficiary’s attending physician based upon a comprehensive assessment and evaluation of the beneficiary after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. (The evaluation generally must be performed within one month prior to initiation of therapy with the air-fluidized bed.)
  □ The course of conservative treatment was at least one month in duration without progression toward wound healing. (This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment was rendered.)
□ Conservative treatment included all of the following six elements:
  □ Frequent repositioning of the beneficiary with particular attention to relief of pressure over bony prominences (usually every 2 hours); and
  □ Use of a Group 2 support surface to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation; and
  □ Necessary treatment to resolve any wound infection; and
  □ Optimization of nutrition status to promote wound healing; and
  □ Debridement by any means, including wet-to-dry gauze dressings, to remove devitalized tissue from the wound bed; and
  □ Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.
In addition, conservative treatment should generally include:
□ Education of the beneficiary and caregiver on the prevention and management of pressure ulcers; and
□ Assessment by a physician, nurse, or other licensed healthcare practitioner at least weekly, and
□ Appropriate management of moisture/incontinence.

An occlusive barrier is required, when necessary, to maintain a moist wound-healing environment that may otherwise be compromised by the drying action of airflow generated by air-fluidized therapy. If moist dressings are NOT required because of the wound characteristics (e.g., heavily exudative wound, etc.), the occlusive barrier is not required as a condition for reimbursement.

Wet-to-dry dressings when used for debridement do not require an occlusive dressing. Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of an air-fluidized bed. Should additional debridement again become necessary while a beneficiary is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to be denied.

□ A trained adult caregiver is available to assist the beneficiary with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of
altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage.

☐ A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis.

☐ All other alternative equipment has been considered and ruled out.


**Documentation Requirements for Continued Coverage Beyond the First Month**

☐ On a monthly basis, the treating physician must document the need for the equipment with a written statement specifying:

☐ The size of the ulcer;

☐ If the ulcer is not healing, what other aspects of the care plan are being modified to promote healing;

☐ Continued use of the bed is reasonable and necessary for wound management.

☐ This monthly physician statement must be kept on file by the supplier and be available for inspection upon request. Continued use is covered until the ulcer is healed.

**Coverage Exclusions**

An air-fluidized bed will be denied as not reasonable and necessary under any of the following circumstances:

- The beneficiary has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);

- The beneficiary requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material;

- The caregiver is unwilling or unable to provide the type of care required by the beneficiary on an air-fluidized bed;

- Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);

- Electrical system is insufficient for the anticipated increase in energy consumption; or

- Other known contraindications exist.

**REMINDERS**

- Suppliers must only add a KX modifier if the criteria in the “Coverage Indications, Limitations and/or Medical Necessity” section of the policy have been met. If the requirements for the KX modifier are not met, the KX modifier must not be used. This information must be available upon request.

- If all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

- Claim lines billed without a KX, GA, or GZ modifier will be rejected as missing information.

- Items delivered before a signed written order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

**ONLINE RESOURCES**

- **JB**: [https://www.cgsmedicare.com/jb/mr/ssr.html]
- **JC**: [https://www.cgsmedicare.com/jc/mr/ssr.html]
• DME MAC Supplier Manual

• Pressure Reducing Support Surfaces - Group 3 LCD and Policy Article
  - JB: https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - JC: https://www.cgsmedicare.com/jc/coverage/lcdinfo.html

NOTE: It is expected that the beneficiary’s medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary’s file.

DISCLAIMER
This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.