Large Volume Nebulizers (A7007, A7017) & Related Compressors (E0565, E0572), Combo Nebulizer w/Compressor & Heater (E0585), Filtered Nebulizer (A7006) & Related Compressors (E0565, E0572)

**REQUIRED DOCUMENTATION**

- **5 Element Order (5EO)** obtained prior to Delivery for the E0585
  - 5 Element order 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 physician.

- **Documentation of Dispensing Order** (preliminary written or verbal order) that contains:
  - Description of the item
  - Prescribing physician/practitioner’s name
  - Name of the beneficiary
  - Date of the order
  - Prescribing physician/practitioner’s signature (if a written order) or supplier signature (if verbal order)

*NOTE:* If the claim includes a combo nebulizer with compressor & heater (E0585), a 5 Element Order must be obtained prior to delivery. A combo nebulizer cannot be delivered based on a dispensing order. A dispensing order for other codes listed in this checklist is only required if the items are dispensed prior to obtaining the detailed written order.

- **Detailed Written Order** (original, faxed, or copied) that contains:
  - Beneficiary’s name
  - Prescribing physician/practitioner’s signature (and date if applicable*)
  - A description of all items, options, accessories or additional features that are separately billed or require an upgraded code. 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.
  - For supplies – list all supplies that are separately billable, and for each include the frequency of use (if applicable), and the quantity dispensed.
  - For drugs used as a supply for a DME item, the written order must include:

*Someone other than the physician/practitioner may complete the DWO of the item unless statute, manual instructions, the contractor’s LCD or policy articles specify otherwise. However, the prescribing physician/practitioner must review the content and sign and date the document.*
The name of the drug and the concentration of the drug in the dispensed solution (Example: Cromolyn 20 mg/2 ml.) or the name of the drug and the number of milligrams/grams of drug in the dispensed solution (Example: Albuterol 2.5 mg and Cromolyn 20 mg in 3 ml saline).

Administration instructions specify the amount of solution and the frequency of use (Example: 3 ml QID and PRN – max 6 doses/24 hr).

- Quantity to be dispensed
- Number of refills
- Any changes or corrections have been initialed/signed and dated by the ordering physician.


**Refill Request**

<table>
<thead>
<tr>
<th>Items Were Obtained In Person at a Retail Store</th>
<th>Written Refill Request Received from the Beneficiary</th>
<th>Telephone Conversation Between Supplier and Beneficiary</th>
</tr>
</thead>
</table>
| □ Signed Delivery Slip  
  □ Beneficiary’s name  
  □ Date  
  □ List of items purchased  
  □ Quantity received  
  □ Signature of person receiving the items  
  OR  
  □ Itemized Sales Receipt  
  □ Beneficiary’s name  
  □ Date  
  □ Detailed list of items purchased  
  □ Quantity received | □ Name of beneficiary or authorized rep (indicate relationship)  
  □ Description of each item being requested  
  □ Date of request  
  □ Quantity of each item beneficiary still has remaining  
  □ Request was not received any sooner than 14 calendar days prior to the delivery/shipping date  
  □ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product | □ beneficiary’s name  
  □ Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary)  
  □ Description of each item being requested  
  □ Date of contact  
  □ Quantity of each item beneficiary still has remaining  
  □ Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date  
  □ Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product |

**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>
</table>
| □ Beneficiary’s name  
  □ Delivery address  
  □ 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.  
  □ Delivery date  
  □ Signature of person accepting delivery  
  □ Relationship to beneficiary | □ Shipping invoice  
  □ Beneficiary’s name  
  □ Delivery address  
  □ 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.  
  □ Quantity shipped  
  □ Tracking slip  
  □ References each individual package  
  □ Delivery address  
  □ Package I.D. #number  
  □ Date shipped  
  □ Date delivered  
  □ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier) | □ Shipping invoice  
  □ Beneficiary’s name  
  □ Delivery address  
  □ 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.  
  □ Quantity shipped  
  □ Date shipped  
  □ Signature of person accepting delivery  
  □ Relationship to beneficiary  
  □ Delivery date |
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.

Claims for Large Volume Nebulizer (A7007, A7017) and Related Compressors (E0565 or E0572)

☐ The medical record supports that it is medically necessary to deliver humidity to a beneficiary with thick, tenacious secretions due to one of the covered conditions listed below.

<table>
<thead>
<tr>
<th>Drugs</th>
<th>HCPCS Codes</th>
<th>Covered Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>A4217</td>
<td>Cystic Fibrosis, Bronchiectasis, Tracheostomy,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or Tracheobronchial Stent</td>
</tr>
<tr>
<td>Saline</td>
<td>A7018</td>
<td></td>
</tr>
</tbody>
</table>

Claims for Combination Nebulizer/Compressor/Heater (E0585)

☐ The medical records include 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 the combo nebulizer in order to administer water or saline.

☐ The medical record supports that it is medically necessary to deliver humidity to a beneficiary with thick, tenacious secretions due to one of the covered conditions listed below.

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Claims for Filtered Nebulizer (A7006) and Compressor (E0565 or E0572)

☐ The medical record supports that it is medically necessary to administer pentamidine to a beneficiary with a covered condition.

<table>
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<th>Covered Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentamidine</td>
<td>J2545</td>
<td>HIV, Pneumocystosis, or complications of organ transplants</td>
</tr>
</tbody>
</table>


☐ Continued Medical Need for the Equipment/Accessories/Supplies is Verified by Either:

☐ A refill order from the treating physician dated within 12 months of the date of service under review; or

☐ A change in prescription dated within 12 months of the date of service under review; or

☐ A medical record, dated within 12 months of the date of service under review that shows usage of the item.

Claims for HCPCS Code E1399 (Miscellaneous Equipment or Accessories)

The claim includes a clear description of the item including:

☐ The manufacturer’s name, ☐ Pricing information, and

☐ The model name/number, ☐ An explanation of medical necessity.
Claims for HCPCS Code J7699 (NOC Nebulizer Drug Code)

The claim is accompanied by:

- Detailed order information as described in the written order requirements,
- A clear statement of the number of ampules/bottles of solution dispensed, and
- Documentation of the medical necessity of the drug for that beneficiary.

ONLINE RESOURCES

- **DME MAC Supplier Manual**

- **Nebulizer LCD and Policy Article**
  - JB: [https://www.cgsmedicare.com/ib/coverage/lcdinfo.html](https://www.cgsmedicare.com/ib/coverage/lcdinfo.html)
  - JC: [https://www.cgsmedicare.com/jc/coverage/lcdinfo.html](https://www.cgsmedicare.com/jc/coverage/lcdinfo.html)

- **Nebulizer Resources**
  - JB: [https://www.cgsmedicare.com/ib/mr/nebulizer_resources.html](https://www.cgsmedicare.com/ib/mr/nebulizer_resources.html)
  - JC: [https://www.cgsmedicare.com/jc/mr/nebulizer_resources.html](https://www.cgsmedicare.com/jc/mr/nebulizer_resources.html)

- **Nebulizer Drug Calculator**
  - JC: [https://www.cgsmedicare.com/jc/Calculators/Nebulizers.html](https://www.cgsmedicare.com/jc/Calculators/Nebulizers.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.

Additionally, while the nebulizer drug LCD does not require suppliers who only provide the nebulizer to keep a file copy of the written order for the drug(s), it is strongly recommended that the supplier do so. In the event of a claim audit by the DME MAC, CERT, or ZPIC contractor, documentation the supplier will be required to submit an order to verify the medical necessity for the nebulizer will include a copy of the detailed written order for the drug(s). Failure to provide the written order in a timely manner could result in denial of the nebulizer claim and an overpayment assessment.

**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.