

# Nebulizers & Inhalation Drugs:

Large Volume (A7007, A7107) & Related Compressors (E0565, E0572), Combo Nebulizer with Compressor & Heater (E0585), Filtered Nebulizer (A7006) & Related Compressors (E0565, E0572)

## MEDICAL REVIEW DOCUMENTATION CHECKLIST

### REQUIRED DOCUMENTATION IN SUPPLIER'S FILE

#### 5 Element Order obtained prior to Delivery for the E0585

5 Element order contains:

Beneficiary's name	Practitioner's signature
Practitioner's NPI	Order date
General description of the item	

The date of the order is on or after a face-to-face encounter between the ordering physician and the beneficiary.

The 5EO was obtained prior to delivery.

A date stamp (or similar) clearly indicates the supplier's date of receipt.

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	Start date of the order (if different from date of the order)
Name of the beneficiary	Physician signature (for written order) or supplier signature (for verbal order)
Name of the physician	
Date of the 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

The treating physician's name

The treating physician's signature

The date the treating physician signed the order (personally entered by the physician)

The date of the order

A list of every separately billable item with refill/replacement instructions

The type of solution to be dispensed is described by either:

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)

Route of administration

Quantity to be dispensed

Number of refills

Any changes or corrections have been initialed/signed and dated by the ordering physician

The physician's signature on the written order meets **CMS Signature Requirements**

<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

REFILL REQUEST		
Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
Signed delivery slip or copy of itemized sales receipt	Name of beneficiary or authorized rep (indicate relationship) Statement that the beneficiary is requesting a refill Description of each item being requested Signature of requestor 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) Statement that the beneficiary is requesting a refill 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																										
Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice																								
Beneficiary's name Quantity delivered Detailed description of item(s) Brand Serial number Delivery date Signature of person accepting delivery Relationship to beneficiary Signature date	<table border="0"> <tr> <td>Shipping invoice</td> <td></td> <td></td> </tr> <tr> <td>Beneficiary's name</td> <td>Quantity shipped</td> <td></td> </tr> <tr> <td>Delivery address</td> <td>Brand</td> <td></td> </tr> <tr> <td>Detailed description of item(s) shipped</td> <td>Serial number</td> <td></td> </tr> <tr> <td>Tracking slip</td> <td></td> <td></td> </tr> <tr> <td>References each individual package</td> <td>Package I.D. #number</td> <td></td> </tr> <tr> <td>Delivery address</td> <td>Date shipped</td> <td></td> </tr> <tr> <td></td> <td>Date delivered</td> <td></td> </tr> </table> <p>A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by supplier)</p>	Shipping invoice			Beneficiary's name	Quantity shipped		Delivery address	Brand		Detailed description of item(s) shipped	Serial number		Tracking slip			References each individual package	Package I.D. #number		Delivery address	Date shipped			Date delivered		Shipping invoice Beneficiary's name Delivery address Detailed description of item(s) shipped Quantity shipped Brand Serial number Date shipped Signature of person accepting delivery Relationship to beneficiary Signature date
Shipping invoice																										
Beneficiary's name	Quantity shipped																									
Delivery address	Brand																									
Detailed description of item(s) shipped	Serial number																									
Tracking slip																										
References each individual package	Package I.D. #number																									
Delivery address	Date shipped																									
	Date delivered																									

### 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 patient with thick, tenacious secretions due to one of the covered conditions listed below.

Drug	HCPCS Code	Covered Condition
Water	A4217	Cystic Fibrosis, Bronchiectasis, Tracheostomy, or Tracheobronchial Stent
Saline	A7018	

### 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.

A date stamp or similar indicator verifies that the supplier received a copy of the F2F note on or before the date of delivery.

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.

Drug	HCPCS Code	Covered Condition
Water	A4217	Cystic Fibrosis, Bronchiectasis, Tracheostomy, or Tracheobronchial Stent
Saline	A7018	

**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.

Drug	HCPCS Code	Covered Condition
Pentamidine	J2545	HIV, Pneumocystosis, or complications of organ transplants

The physician's signature on the medical records meets **CMS Signature Requirements**  
<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

**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,
- The model name/number,
- Pricing information, and
- 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.

**Additional Information References on the Web**

- Supplier Documentation Requirements: <http://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf>
- Nebulizer LCD and Policy Article: <http://www.cgsmedicare.com/jc/coverage/LCDInfo.html>
- Nebulizer Resources: [http://www.cgsmedicare.com/jc/coverage/mr/Nebulizer\\_Resources.html](http://www.cgsmedicare.com/jc/coverage/mr/Nebulizer_Resources.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 in 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 Jurisdiction C Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.