

# Nebulizers & Inhalation Drugs:

Small Volume Nebulizers (A7003, A7004, A7005) & Related Compressor (E0570)

## MEDICAL REVIEW DOCUMENTATION CHECKLIST

### REQUIRED DOCUMENTATION IN SUPPLIER'S FILE

#### Documentation of Dispensing Order (preliminary written or verbal order) that contains:

Description of the item	Date of the order
Name of the beneficiary	Physician signature (for written order) or supplier signature (for verbal order)
Name of the physician	

**NOTE:** If the claim includes a nebulizer with compressor (HCPCS code E0570), a detailed written order must be obtained prior to delivery. A nebulizer with compressor cannot be delivered based on a dispensing order. A dispensing order for related supplies and inhalation drugs is only required if these 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 NPI  
 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 and the volume of solution in each container (**Example:** Cromolyn 20 mg/2 ml) **or**  
 The name of the drug and the number of milligrams/grams of drug in the dispensed solution and the volume of solution in that container (**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  
 A date stamp (or similar) clearly indicates the supplier's date of receipt (for orders that include E0570)

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	Shipping invoice  Beneficiary's name Delivery address Detailed description of item(s) shipped  Tracking slip  References each individual package Delivery address  A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by supplier)	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

#### Medical Records

If the claim includes a nebulizer with compressor (E0570), 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 a nebulizer with compressor in order to administer inhalation drugs.

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 administer one of the following inhalation drugs for one of the listed covered conditions.

Drug	HCPCS Code	Covered Condition
Albuterol	J7611, J7613	Obstructive Pulmonary Disease
Arformoterol	J7605	
Budesonide	J7626	
Cromolyn	J7631	
Formoterol	J7606	
Ipratropium	J7644	
Levalbuterol	J7612, J7614	
Metaproterenol	J7669	
Dornase Alfa	J7639	Cystic Fibrosis
Tobramycin	J7682	Cystic Fibrosis or Bronchiectasis
Pentamidine	J2545	HIV, Pneumocystosis, or complications of organ transplantation
Acetylcysteine	J7608	Persistent thick or tenacious pulmonary secretions

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 a Small Volume Ultrasonic Nebulizer (E0574)

A small volume ultrasonic nebulizer is reasonable and necessary to administer treprostinil inhalation solution only (See Treprostinil/Iloprost Inhalation Solution Checklist). Claims for code E0574 used with other inhalation solutions will be denied as not reasonable and necessary.

#### 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.