

DOCUMENTATION CHECKLIST



NEBULIZERS AND INHALATION DRUGS

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

REQUIRED DOCUMENTATION

Standard Written Order (original, faxed, or copied) that contains:

Beneficiary's name or Medicare Beneficiary Identifier (MBI)

Order date

General description of the item

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 equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).

For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (List each separately)

Quantity to be dispensed, if applicable

Treating Practitioner Name or NPI

Treating Practitioner's signature

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

Treating practitioner's signature on the written order meets **CMS Signature Requirements**

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>

For drugs used as a supply for a DME item, the written order may include:

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 Quantity to be dispensed)

Administration instructions specify the amount of solution and the frequency of use

Number of refills



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Refill Request

For dates of service prior to January 1, 2024

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 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

For dates of service on and after January 1, 2024

Items Were Obtained In Person at a Retail Store	Delivered Refill Communications
Signed delivery slip or copy of itemized sales receipt Delivery slip/receipt should indicate items were picked up at store front	Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) Date of Request Description of each item requested Documentation of affirmative response indicating a need for the refill Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

Delivery Documentation

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
Beneficiary's name Delivery address Quantity delivered 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.

Medical Records

The medical record supports that it is medically necessary to administer one of the following inhalation drugs for one of the listed covered conditions (the medical record should contain the name of the drug in nebulizer form and the condition).

Drug	HCPCS Code	Covered Condition
Albuterol	J7611, J7613	Obstructive Pulmonary Disease
Arformoterol	J7605	
Budesonide	J7626	
Cromolyn	J7631	
Duoneb	J7620	
Formoterol	J7606	
Ipratropium	J7644	
Levalbuterol	J7612, J7614	
Metaproterenol	J7669	
Revefenacin	J7677	
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

Treating practitioner’s signature on the written order meets **CMS Signature Requirements**
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Continued Medical Need for the equipment/accessories/supplies within 12 months of the date of service is verified by:

- A recent order/prescription by the treating practitioner for refills of supplies; or
 - A recent order/prescription by the treating practitioner for repairs; or
 - A recent change in an order/prescription; or
 - Timely documentation in the beneficiary’s medical record showing usage of the item.
- Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

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:

- 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**
 - **JB:** <https://www.cgsmedicare.com/jb/pubs/supman/index.html>
 - **JC:** <https://www.cgsmedicare.com/jc/pubs/supman/index.html>
- **Nebulizer LCD and Policy Article**
 - **JB:** <https://www.cgsmedicare.com/jb/coverage/lcdinfo.html>
 - **JC:** <https://www.cgsmedicare.com/jc/coverage/LCDinfo.html>
- **Nebulizer Resources**
 - **JB:** https://www.cgsmedicare.com/jb/mr/nebulizer_resources.html
 - **JC:** https://www.cgsmedicare.com/jc/mr/nebulizer_resources.html
- **Nebulizer Drug Calculator**
 - **JB:** <https://www.cgsmedicare.com/jb/Calculators/Nebulizers.html>
 - **JC:** <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, RAC or UPIC 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 Standard Written Order for the drug(s). Failure to provide the written order in a timely manner could result in denial of the claim.

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.