

DOCUMENTATION CHECKLIST

NEBULIZERS AND INHALATION DRUGS

Small Volume Nebulizers (A7003, A7004, A7005)
& Related Compressor (E0570)**REQUIRED DOCUMENTATION****5 Element Order (5EO) obtained prior to Delivery for E0570**

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

Name of the beneficiary

Prescribing physician/practitioner's name

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 nebulizer with compressor (HCPCS code E0570), a 5EO 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

Prescribing physician/practitioner's signature (and date if applicable*)

* *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 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)



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

Physician'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>

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 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

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
Beneficiary's name 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 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. Signature of person accepting delivery Relationship to beneficiary Delivery 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.

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).

Table with 3 columns: Drug, HCPCS Code, Covered Condition. Rows include Albuterol, Arformoterol, Budesonide, Cromolyn, Duoneb, Formoterol, Ipratropium, Levalbuterol, Metaproterenol, Dornase Alfa, Tobramycin, Pentamidine, and Acetylcysteine.

Physician'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

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.

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, 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.