

DOCUMENTATION CHECKLIST

NEBULIZERS & INHALATION DRUGS

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

REQUIRED DOCUMENTATION

Standard Written Order (SWO) 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

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

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)

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

The 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>



Refill Request

<i>*For dates of service prior to January 1, 2024*</i>		
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

<i>*For dates of service on and after January 1, 2024*</i>	
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:

- 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.
- 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.

Drugs	HCPCS Codes	Covered Conditions
Water	A4217	Cystic Fibrosis, Bronchiectasis, Tracheostomy, or Tracheobronchial Stent
Saline	A7018	

Claims for Combination Nebulizer/Compressor/Heater (E0585)

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.

Drugs	HCPCS Codes	Covered Conditions
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.

Drugs	HCPCS Codes	Covered Conditions
Pentamidine	J2545	HIV, Pneumocystosis, or complications of organ transplants

Practitioner’s Signature

The treating practitioner’s signature on the medical records meets CMS Signature Requirements <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>

Continued Medical Need

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

- A recent order/prescription by the treating practitioner for refills of supplies;
- A recent order/prescription by the treating practitioner for repairs;
- A recent change in an order/prescription;
- 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 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:

- 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 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 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.