

DOCUMENTATION CHECKLIST

NEBULIZERS AND INHALATION DRUGS

Iloprost (Q4074) and Treprostinil (J7686) Inhalation Solution
Controlled Dose Inhalation Drug Delivery System (K0730)
and Small Volume Ultrasonic Nebulizer (E0574)

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 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: Iloprost 10 mcg/1mL.)
 - Administration instructions specify the amount of solution and the frequency of use (Example: 0.5 mL every 2 hours during waking hours – not to exceed 9 times per day)
 - Number of refills
- 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**

Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
<input type="checkbox"/> Signed Delivery Slip <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Date <input type="checkbox"/> List of items purchased <input type="checkbox"/> Quantity received <input type="checkbox"/> Signature of person receiving the items OR <input type="checkbox"/> Itemized Sales Receipt <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Date <input type="checkbox"/> Detailed list of items purchased <input type="checkbox"/> Quantity received 	<input type="checkbox"/> Name of beneficiary or authorized rep (indicate relationship) <input type="checkbox"/> Description of each item being requested <input type="checkbox"/> Date of request <input type="checkbox"/> Quantity of each item beneficiary still has remaining <input type="checkbox"/> Request was not received any sooner than 14 calendar days prior to the delivery/shipping date <input type="checkbox"/> Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product	<input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Name of person contacted (if someone other than the beneficiary include this person's relationship to the beneficiary) <input type="checkbox"/> Description of each item being requested <input type="checkbox"/> Date of contact <input type="checkbox"/> Quantity of each item beneficiary still has remaining <input type="checkbox"/> Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date <input type="checkbox"/> 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
<input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> Quantity delivered <input type="checkbox"/> 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. <input type="checkbox"/> Delivery date <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary	<input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> 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. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Tracking slip <ul style="list-style-type: none"> <input type="checkbox"/> References each individual package <input type="checkbox"/> Delivery address <input type="checkbox"/> Package I.D. #number <input type="checkbox"/> Date shipped <input type="checkbox"/> Date delivered <input type="checkbox"/> 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)	<input type="checkbox"/> Shipping invoice <ul style="list-style-type: none"> <input type="checkbox"/> Beneficiary's name <input type="checkbox"/> Delivery address <input type="checkbox"/> 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. <input type="checkbox"/> Quantity shipped <input type="checkbox"/> Date shipped <input type="checkbox"/> Signature of person accepting delivery <input type="checkbox"/> Relationship to beneficiary <input type="checkbox"/> 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.

Claims for a Controlled Dose Drug Delivery System (K0730)

- The medical records documents that the beneficiary was evaluated and/or treated for pulmonary hypertension and needs a K0730 in order to deliver Iloprost (Q4074).

Claims for a Small Volume Ultrasonic Nebulizer (E0574)

- The device is being used to administer treprostinil inhalation solution (J7686)

Claims for Treprostinil Inhalation Solution (J7686) and Iloprost (Q4074)

- The medical records support that the beneficiary has pulmonary artery hypertension; and
- The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.), and
- The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the medical record must show that all the following criteria are met:
 - The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
 - The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; and
 - The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
 - Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.



Continued Medical Need for the Equipment/Accessories/Supplies is verified by either:

- A refill order from the treating practitioner 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.

REMINDERS

- If all the coverage criteria have been met for K0730, Q4074, E0574 or J7686, a KX modifier must be added to the code(s).
- If all of the coverage criteria have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or GZ if they have not obtained a valid ABN.
- Claim lines for K0730, Q4074, E0574 or J7686 billed without a KX, GA, or GZ modifier will be rejected as missing information.
- If a controlled dose inhalation drug delivery system (K0730) is used to administer any inhalation solution other than Iloprost (Q4074), the claim will be denied as not reasonable and necessary.
- Items with no physician or other licensed health care provider order must be submitted with an "EY" modifier added to each affected HCPCS code.
- If a small volume nebulizer (E0574) is used to administer any inhalation solution other than Treprostinil (J7686), the claim will be denied as not reasonable and necessary.

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

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.