DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

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**

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.

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) to beneficiaries with pulmonary hypertension only

Claims for Treprostinil Inhalation Solution (J7686)

Treprostinil inhalation solution (J7686) is considered for coverage when either criteria 1-3; or, criterion 4 are met:

☐ 1. The beneficiary has a diagnosis of pulmonary artery hypertension; and

☐ 2. The pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system other than interstitial lung disease; and

☐ 3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the following criteria (a-d) must be met:

- ○ a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
- ○ b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and
- ○ c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
- ○ d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

☐ 4. The beneficiary has a diagnosis of pulmonary hypertension associated with interstitial lung disease and the following criteria (a-e) are met:

- ○ a. The presence of interstitial lung disease has been confirmed by a high-resolution CT scan of the chest; and
- ○ b. The mean pulmonary artery pressure is ≥ 25 mm Hg; and
- ○ c. The pulmonary capillary wedge pressure or left ventricular end-diastolic pressure is ≤ 15mm Hg; and
- ○ d. The pulmonary vascular resistance is ≥ 3 Wood Units at rest; and
- ○ e. The beneficiary has significant symptoms of pulmonary hypertension (e.g., dyspnea on exertion, fatigability)

Claims for Iloprost (Q4074) Solution

Iloprost (Q4074) is considered for coverage when all of the following criteria 1-3 are met:

☐ 1. The beneficiary has a diagnosis of pulmonary artery hypertension; and

☐ 2. The pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system and

☐ 3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the following criteria (a-d) must be met:

- ○ a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and

- ○ b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and
- ○ c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
- ○ d. 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 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.

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.