Nebulizers & Inhalation Drugs:

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

MEDICAL REVIEW DOCUMENTATION CHECKLIST

REQUIRED DOCUMENTATION IN SUPPLIER'S FILE

- ☐ Documentation of Dispensing Order (preliminary written or verbal order) that contains:
  - ☐ Description of the item
  - ☐ Name of the beneficiary
  - ☐ Name of the physician
  - ☐ Date of the order
  - ☐ Physician signature (for written order) or supplier signature (for verbal order)

NOTE: If the claim includes a controlled dose inhalation drug delivery system (K0730), a detailed written order must be obtained prior to delivery. A controlled dose inhalation drug delivery system 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
  - ☐ The treating physician's name
  - ☐ The treating physician's NPI
  - ☐ The treating physician's signature
  - ☐ The date the treating physician signed the order (personally entered by the physician
  - ☐ The date of the order
  - ☐ A list of every separately billable item with refill/replacement instructions
  - ☐ The name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container (Example: Iloprost 10 mcg/1 mL)
  - ☐ 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)
  - ☐ Route of administration
  - ☐ Quantity to be dispensed
  - ☐ Number of refills
  - ☐ Any changes or corrections have been initialed/signed and dated by the ordering physician
  - ☐ A date stamp (or similar) clearly indicates the supplier's date of receipt (for orders that include K0730)
- ☐ 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)
- ☐ The physician's signature on the written order meets **CMS Signature Requirements** http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html

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 or copy of itemized sales receipt	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Statement that the beneficiary is requesting a refill ☐ Description of each item being requested ☐ Signature of requestor ☐ 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) ☐ Statement that the beneficiary is requesting a refill ☐ 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 ☐ Detailed description of item(s) ☐ Brand ☐ Serial number ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary ☐ Signature date	☐ Shipping invoice ☐ Beneficiary's name ☐ Delivery address ☐ Detailed description of item(s) shipped ☐ Quantity shipped ☐ Brand ☐ Serial number ☐ 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 supplier)	☐ Shipping invoice ☐ Beneficiary's name ☐ Delivery address ☐ Detailed description of item(s) shipped ☐ Quantity shipped ☐ Brand ☐ Serial number ☐ Date shipped ☐ Signature of person accepting delivery ☐ Relationship to beneficiary ☐ Signature date

Medical Records

Claims for a Controlled Dose Drug Delivery System (K0730)

☐ 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 pulmonary hypertension and needs a K0730 in order to deliver Iloprost (Q4074).
- ☐ A date stamp or similar indicator verifies that the supplier received a copy of the F2F note on or before the date of delivery.

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 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.

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.
- 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.

Additional Information References on the Web

- Supplier Documentation Requirements: http://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf
- Nebulizer LCD and Policy Article: http://www.cgsmedicare.com/jc/coverage/LCDinfo.html
- Nebulizer Resources: http://www.cgsmedicare.com/jc/coverage/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, or ZPIC contractor, documentation the supplier will be required to submit in 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 Jurisdiction C Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.