



Medicare Part C Medical Coverage Policy

Nebulizer Medications

Origination: June 17, 2009
Review Date: October 20, 2021
Next Review: October 2023

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION

Nebulizer medications are used to prevent and treat wheezing, difficulty breathing and chest tightness caused by lung diseases such as asthma and chronic obstructive pulmonary disease (COPD). They work by relaxing and opening air passages to the lungs to make breathing easier.

POLICY STATEMENT

Coverage will be provided for nebulizers when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

PART B COVERAGE CRITERIA:

1. **Preauthorization by the Plan may be required;**

2. FDA-approved inhalation solutions of the drugs listed below using a small volume nebulizer and related compressor are covered when:
 - a) The administration of albuterol, arformoterol, budesonide, cromolyn, formoterol, ipratropium, levalbuterol, metaproterenol, or revefenacin for the management of obstructive pulmonary disease (ICD-10; J41.0-J70.9); **or**
 - b) The administration of dornase alpha to a member with cystic fibrosis (ICD-10; E84.0); **or**
 - c) The administration of tobramycin to a member with cystic fibrosis or bronchiectasis (ICD-10; E84.0), (ICD-10; J47.9), (ICD-10; J47.1), (ICD-10; Q33.4) or (ICD-10; A15.0-A15.9); **or**
 - d) The administration of pentamidine to a members with HIV, (ICD-10; B20.), pneumocystosis (ICD-10; B59), or complications of organ transplants (ICD-10; T86.890; T86.891; T86.899); **or**
 - e) The administration of acetylcysteine for persistent thick or tenacious pulmonary secretions (ICD-10; J12.0; J70.9); (ICD 10; R09.3).
3. A large volume nebulizer, related compressor, and water or saline are covered when it is medically necessary to deliver humidity to a member with thick, tenacious secretions who has cystic fibrosis, (ICD 10; R09.3), bronchiectasis (ICD-10; J47.9), (ICD-10; J47.1), (ICD-10; A15.0) or (ICD-10; Q33.4), a tracheostomy (ICD-10; Z93.0 or V55.0), or a tracheobronchial stent (ICD 10; J39.8 and J98.09).
4. An E0565 or E0572 compressor and filtered nebulizer (A7006) are also covered when it is reasonable and necessary to administer pentamidine to members with HIV (ICD-10; B20), pneumocystosis (ICD 10; B59); or complications of organ transplants (ICD 10; T86.90; T86.91; T86.92; T86.99) and, (ICD 10; T86.890; T86.89; T86.899).
5. **Trespostinil inhalation solution and Iloprost** is covered when all the following criteria 1-3 below are met:
 - a) The member has a diagnosis of pulmonary artery hypertension, (ICD-10; I27.0) or (ICD 10; I27.2; I27.89); **and**
 - b) 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**

- c) The member 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, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria (a-d) must be met:
 - i. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; **and**
 - ii. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; **and**
 - iii. The member has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); **and**
 - iv. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT

A. When the above criteria are not met.

B. Aztreonam lysine is an inhalation solution that is indicated for members with cystic fibrosis with chronic *Pseudomonas aeruginosa* infection. Medicare has determined that the nebulizer that is FDA-approved for administration of aztreonam lysine is not sufficiently durable to meet the requirements for coverage under the DME benefit for that nebulizer, therefore aztreonam lysine inhalation solution and related accessories will be denied as noncovered (no Medicare benefit).

C. Compounded inhalation solutions (J7604, J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7632, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7676, J7680, J7681, J7683, J7684, J7685, and compounded solutions billed with J7699) will be denied as not reasonable and necessary.

NOTE: Code Q9977 Compounded Drug, Not Otherwise Classified, does not apply to compounded nebulizer drugs.

D. A large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor and nebulizer and will be denied as not reasonable and necessary.

E. A prefilled disposable large volume nebulizer (A7008) is considered a convenience item and is noncovered.

PART D COVERAGE CRITERIA:

A. Preauthorization by the Plan is required;

1. If the above criteria are not met for coverage under the Part B benefit, the medication may be covered under Part D if:
 - a. The medication is administered for an FDA approved use;
 - b. The medication is on a prescription from a physician;
 - c. The medication is used and sold in the United States
 - d. The medication is used for a medically accepted indication.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: E0565, E0570, , E0572, E0574, E0575, E0580, E0585, K0730, A4216, A4217, A4218, A7018, G0333, J2545, J7604 , J7605, J7606, J7607 , J7608, J7609 , J7610 , J7611, J7612, J7613, J7614, J7615 , J7620, J7622 ,J7624, , J7626, J7627, J7628, J7629, J7631, J7632, J7634, J7635, J7636, J7637, J7638, J7639, J7640, J7641, J7642, J7643, J7644, J7645, J7647, J7650, J7657, J7660, J7667, J7669, J7670, J7676, J7680, J7681, J7682, J7683, J7684, J7685, J7686, J7699, Q0513, Q0514, Q4074.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

- A. Inhalation drugs used with a nebulizer are not covered under Part B in the case of a member in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out, or whose stay is non-covered because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. (See list below for other facilities which cannot be considered a beneficiary's "home" for DME purposes.)
 - 1) In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Plan DME benefit:
 - a. A nursing home that is dually-certified as both an Original Medicare SNF and a Medicaid nursing facility (NF);
 - b. A Medicaid-only NF that primarily furnishes skilled care;
 - c. A non-participating nursing home (i.e. neither Original Medicare or Medicaid) that provides primarily skilled care; and
 - d. An institution which has a distinct part SNF and which also primarily furnishes skilled care.

- B. Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler, dry powder inhaler, nasal spray or other non-nebulized administration, they would be Part D drugs.

References:

1. Medicare Local Coverage Determination for Nebulizers (ID#L33370); Effective date: 10/01/2015. Accessed via Internet site at www.cms.gov; Medicare Article for Nebulizers (ID#A52466); Effective date: 10/01/2015. Accessed via Internet site on <http://www.cgsmms.gov>. Viewed on 10/4/21.
2. Medicare Part B Versus Part D Coverage Issues document; Effective 7/27/05; Accessed via Internet site: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/BvsDCoverageIssues.pdf>; viewed on 10/8/19.
3. Medicare Local Coverage Article for Nebulizers (A52466); Effective Date 10/01/15. Accessed via www.cms.gov; viewed on 10/4/21.

Policy Implementation /Update Information:

Revision Date: New policy June 17, 2009, Revision date: March 2010, Change in CMS criteria.

Revision Date 3/30/11: Indications For Coverage section: added coverage indications for Trespostinil inhalation solution under item #4 per updated CMS policy LCD L5007, moved the paragraph pertaining to a controlled dose inhalation drug delivery system...under the Note section after coverage criteria. Added language under item B. pertaining to Aztreonam lysine under When Coverage Will Not Be Approved section and added item B. pertaining to non-coverage of Aztreonam lysine.

Coding section: Updated per Senior Coding Analyst.

Reference section: Updated to reflect updated CMS policy.

Revision Date 8/25/11: Revision 8/25/11: Added language and codes regarding non-coverage of compound drugs.

Revision Date: 10/7/2013; Annual review; Listed ICD-10 codes; added note to cover E0565 to administer Pentamidine for given diagnosis; Minor edits to clarify policy for staff.

Revision Date: 10/21/2015; Annual Review; Indications For coverage – minor edits for policy consistency; When Coverage Will Not Be Approved – added items D and E along with reference to code Q9977 under item C per LCD; Reference section updated with new LCD per the ICD-10 update.

Revision Date: 10/18/17; Annual Review; No CMS Updates. Added Reference to Medicare Local Coverage Article. Minor revisions only.

Revision Date: 10/16/19; Annual Review. No CMS Updates. Minor Revisions Only.

Revision Date: 10/20/21; Annual Review. Indications for Coverage: Addition of 2. A) "or revefenacin" for consistency with LCD.

Approval Dates:

Medical Coverage Policy Committee: October 20, 2021

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator