

September 2018

NEBULIZERS - COVERAGE CRITERIA AND CLINICIAN DOCUMENTATION REQUIREMENTS

Dear Clinician,

Inhalation drugs are covered by Medicare Part B when the patient has a chronic pulmonary condition that will benefit from the use of inhalation therapy and they are administered using a durable medical equipment (DME) type of nebulizer (e.g., aerosol pneumatic compressor). Inhalation drugs administered using metered dose inhalers or similar devices are eligible for coverage by Medicare Part D but not the Medicare Part B DME benefit. The information in this letter addresses only those drugs administered using a DME nebulizer.

Inhalation drugs, nebulizers, and related accessories are covered for the following conditions:

- **Chronic Obstructive Pulmonary Disease (COPD):** Beta agonists (albuterol, arformoterol, formoterol, levalbuterol, metaproterenol), anti-cholinergics (ipratropium), corticosteroids (budesonide), and cromolyn.
- **Cystic Fibrosis:** Dornase alpha, tobramycin
- **Bronchiectasis:** Tobramycin, acetylcysteine
- **HIV, pneumocystosis or complications of organ transplants:** Pentamidine
- **Pulmonary hypertension:** Iloprost, treprostiril
- **Thick/tenacious pulmonary secretions:** Acetylcysteine

Medicare covers only FDA-approved formulations of inhalation drugs. Compounded inhalation solutions are not covered.

Medicare also covers DME nebulizers and accessories when they are needed to provide humidification for patients with thick/tenacious secretions who have a diagnosis of cystic fibrosis or bronchiectasis or who have a tracheostomy or tracheobronchial stent.

The local coverage determination (LCD) on nebulizers identifies the usual maximum daily dose of inhalation drugs that is covered by Medicare. Of particular note is budesonide which is covered at a maximum dosage of 0.5 mg twice per day or 1.0 mg once per day. Refer to the LCD for information about the maximum covered quantities of other drugs or about the coverage of combinations of drugs in the same therapeutic class.

For most inhalation drugs, Medicare covers administration using standard aerosol pneumatic compressor-type nebulizers. Refer to the LCD for details on the coverage of specific nebulizers.

When you are initially ordering inhalation drugs, nebulizers, and accessories it is important that you clearly document in your medical records the patient's diagnosis and other clinical information relating to their need

for these items. Simply listing that information on the order or on a form provided by the supplier is not sufficient.

On an ongoing basis, when you see your patient for follow-up visits, it is important that you document the continued need for and use of inhalation drugs and nebulizer—just as you document the need for other medications and equipment that they are using.

For the nebulizer compressor only, 42 CFR 410.38 requires an in-person, face-to-face examination to document evaluation and/or treatment for a condition that supports the need for the item(s) of DME ordered. The face-to-face examination must have occurred sometime during the six (6) months prior to the date of the order for the item. 42 CFR 410.38 also requires a specific written order prior to delivery for the nebulizer compressor.

Clinicians can view the complete Nebulizer Local Coverage Determination and related Policy Articles on the Noridian website at <https://med.noridianmedicare.com>. It may also be viewed in the local coverage section of the Medicare Coverage Database at <https://www.cms.gov/medicare-coverage-database/>.

Suppliers may ask you to provide the documentation from your medical records on a routine basis in order to assure that Medicare will pay for these drugs and that your patient will not be held financially liable. Providing this documentation is in compliance with the Health Insurance Portability and Accountability Act Privacy Rule. No specific authorization is required from your patient. Also note that you may not charge the supplier or the beneficiary to provide this information. Please cooperate with the supplier so that they can provide the inhalation drugs and nebulizers that are needed by your patient.

Sincerely,

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