

December 2010

Nebulizers – Coverage Criteria and Physician Documentation Requirements

Dear Physician,

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 compressor or ultrasonic nebulizer). Inhalation drugs administered using metered dose inhalers or similar devices are eligible for coverage by Medicare Part D. 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:

- Beta agonists (albuterol, arformoterol, formoterol, levalbuterol, metaproterenol), anti-cholinergics (ipratropium), corticosteroids (budesonide), and cromolyn for obstructive pulmonary disease;
- Dornase alpha for cystic fibrosis;
- Tobramycin for cystic fibrosis or other causes of bronchiectasis;
- Pentamidine for HIV, pneumocystosis, and complications of organ transplants;
- Mucolytics (acetylcysteine) for thick/tenacious pulmonary secretions;
- Pulmonary artery vasodilators (iloprost, treprostinil) for pulmonary hypertension.

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 compressor type nebulizers. Patients will have to pay the upcharges for ultrasonic or other electronic 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 nebulizers—just as you document the need for other medications that they are using.

There must be a detailed written order that lists the drug(s) with the dosage and frequency of administration, the nebulizer, and related accessories. This document may be prepared by the supplier, but you must review it, initial and date any changes, and then personally sign and date the order. Signature and date stamps are not acceptable. Verbal orders alone are not sufficient for Medicare coverage.

Physicians can view the complete local coverage determination and policy article titled Nebulizers on the National Government Services Web site at www.NGSMedicare.com. It may also be viewed in the local coverage section of the Medicare Coverage Database at www.cms.hhs.gov/mcd/search.asp

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,

Stacey V. Brennan, M.D., FAAFP
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