IEHP UM Subcommittee Approved Authorization Guidelines

Nebulizers

Policy:

Medically Necessary:
A small volume nebulizer and related compressor is considered medically necessary when any of the following criteria are met:

1. When it is medically necessary to administer gentamicin, tobramycin, amikacin or dornase alfa as part of the treatment of cystic fibrosis; or
2. When it is medically necessary to administer pentamidine for the prevention or treatment of the complications of HIV or organ transplants, (i.e., pneumocystis pneumonia [PCP]); or
3. When it is medically necessary to administer mucolytics (other than dornase alfa) for persistent thick or tenacious pulmonary secretions; or
4. When it is medically necessary to administer beta-adrenergics, anticholinergics, corticosteroids, and cromolyn for the management of obstructive pulmonary disease (either chronic obstructive pulmonary disease or asthma).

In order for the medical necessity criterion to be met for chronic obstructive pulmonary disease or asthma, use of a metered dose inhaler (MDI) with/without a reservoir or spacer device must have been considered by the treating physician and determined to be ineffective/insufficient for the administration of the inhalation drug(s), based on medical rationale.

A large volume nebulizer, related compressor and water or saline are considered medically necessary to deliver humidity to patients with thick, tenacious secretions for any of the following conditions:

- Cystic fibrosis; or
- Bronchiectasis; or
- Persons with a tracheostomy; or
- Patients with a tracheobronchial stent.

Other uses of compressors/generators will be considered on a case-by-case basis to determine medical necessity.

Note: Dornase alfa is only considered medically necessary for individuals with cystic fibrosis.
Use of more than one nebulizer device (at the same time) is considered medically necessary when nebulized dornase alpha plus other nebulized medications are prescribed. FDA-approved product labeling of dornase alpha instructs that this medication should not be diluted or mixed with other drugs in the same nebulizer. The labeling explains that mixing of dornase alpha with other drugs could lead to adverse physiochemical and/or functional changes in dornase alpha or in the admixed compound.

Not Medically Necessary:
Use of inhalation drugs, other than those listed above, including the nebulizer and its accessories/supplies, is considered not medically necessary.

The following types and uses for nebulizers are considered not medically necessary:

- Large volume nebulizers (and related compressor/generator and water/saline) when used primarily to provide room humidification; and
- All ultrasonic nebulizers, both large and small volume types (and related accessories/supplies) for all indications; and
- Disposable large volume pneumatic nebulizers (convenience item); and
- Kits and concentrates for use in cleaning respiratory equipment; and
- Battery-powered compressors for all indications, subject to individual case-by-case consideration.

Background:
Nebulizer devices are used as part of the treatment plan for a variety of pulmonary conditions, including, but not limited to, asthma, cystic fibrosis, and pneumonia, amongst others. There are several types of nebulizers currently marketed, including forced air (pneumatic) models, which utilize a compressor, and ultrasonic models that use ultrasound wave vibrations, produced by an ultrasonic generator, to transform the water-soluble medications into a mist. The term nebulizer is generally used for the actual chamber, in which the nebulization of liquid occurs and is an accessory to the equipment. The nebulizer is attached to an aerosol compressor or to an ultrasonic generator in order to achieve a functioning delivery system for aerosol therapy.

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Bibliography:
2. Anthem Clinical UM Guideline: Nebulizers. #: CG-DME-14; 1/14/22009.


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