

Nebulized Medications Drug Use Criteria

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Includes: All nebulized medications with FDA-approved nebulized formulations billed under the pharmacy benefit.

REQUIREMENT

Coverage of nebulized medications is based on medical necessity for nebulized drug delivery, consistent with OHA rules and existing Advanced Health Nebulizer Machine Drug Use Criteria.

- Members who already possess a nebulizer machine are not required to submit a simultaneous PA request for a nebulizer machine.
- Members without access to a nebulizer machine must meet criteria for nebulizer machine approval prior to medication approval.

Initial Request: All criteria below must be met.

Renewal Request: Ongoing medical necessity must be documented.

EXCLUSIONS

Nebulized medications will not be approved when:

- The member does not have access to a nebulizer machine
- An equivalent inhaled formulation is clinically appropriate and effective
- The requested medication is not FDA-approved for nebulized administration

GUIDELINE FOR USE:

Initial Authorization

1. Is the request submitted with a complete prior authorization (PA) request, including diagnosis and the requested nebulized medication?
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Does the member have access to a nebulizer machine, defined as either:
 - Current or prior approval for a nebulizer machine under Advanced Health criteria, OR
 - Documentation that the member already has a nebulizer machine available for use in the home?

Note: Members without a nebulizer must first meet Nebulizer Machine Drug Use Criteria.

- a. If yes, go to 3.
 - b. If no, deny as not meeting criteria.
3. Does the member have a covered diagnosis consistent with OHA guidelines for nebulized therapy (e.g., COPD with airflow limitation confirmed by PFT, moderate to severe asthma, bronchiectasis, cystic fibrosis, tracheostomy with secretion management, or other diagnoses requiring nebulized drug delivery)?
 - a. If yes, go to 4.
 - b. If no, deny as not meeting criteria.
 4. Is the requested medication an FDA-approved nebulized formulation for the member's diagnosis?
 - a. If yes, go to 5.
 - b. If no, deny as not meeting criteria.
 5. Is there documentation that a metered-dose inhaler (MDI) or dry powder inhaler (DPI):
 - was attempted and found insufficient, OR
 - is contraindicated for the member?

Note: Poor inhaler technique alone does not constitute treatment failure. Member education on proper inhaler use, with spacer and/or mask when appropriate, should be attempted when technique issues are identified.

- a. If yes, go to 6.
 - b. If no, deny as not meeting criteria.
6. Is the requested nebulized medication consistent with the clinical indication for nebulized delivery and requested at an FDA-approved dose and frequency?
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as not meeting criteria.

Renewal Authorization

1. Does the member continue to have access to a nebulizer machine (existing home nebulizer or approved equipment)?
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Is there documentation demonstrating continued clinical benefit from the nebulized medication (e.g., symptom improvement, reduced exacerbations, improved pulmonary status)?
 - a. If yes, go to 3.
 - b. If no, deny as not meeting criteria.

3. Is the requested dose and quantity within FDA labeling and consistent with clinical guidelines?
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as not meeting criteria.

Rationale: This policy extends the clinical framework used in the Advanced Health Nebulizer Machine Drug Use Criteria to nebulized medications, ensuring consistent application of OHA rules while avoiding unnecessary duplication of equipment prior authorization. Allowing members with an existing nebulizer to proceed directly to medication review reduces administrative burden while maintaining appropriate utilization and medical necessity standards consistent with OAR 410-122-0204

References:

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