

Clinical Policy: Antibiotics, Inhaled

Reference Number: PHW.PDL.240

Effective Date: 01/01/2020

Last Review Date: 11/2025

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Inhaled Antibiotics are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Antibiotics, Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotic, Inhaled.
2. An Antibiotic, Inhaled with a prescribed quantity that exceeds the quantity limit.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. For a non-preferred Antibiotic, Inhaled, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antibiotics, Inhaled approved for the member's diagnosis

- b. Has culture and sensitivity test results that document that only a non-preferred Antibiotic, Inhaled will be effective;

AND

- 5. If a prescription for an Antibiotic, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. Approval Duration:

- **New request: 6 months**
- **Renewal request: 12 months**

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024
Q1 2026 annual review: no changes.	11/2025