



<b>ISSUE DATE</b> June 27, 2019	<b>EFFECTIVE DATE</b> July 8, 2019	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Antibiotics, Inhaled – Pharmacy Services		<b>BY</b>  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Antibiotics, Inhaled submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Antibiotics, Inhaled to the appropriate managed care organization.

**BACKGROUND/DISCUSSION:**

Arikayce (amikacin liposome inhalation suspension) is a new agent in the Antibiotics, Inhaled Preferred Drug List (PDL) drug class. It is Food and Drug Administration (FDA) approved for the treatment of adults who have limited or no alternative treatment options for the treatment of *Mycobacterium avium* complex. Arikayce is the only drug in the Antibiotics, Inhaled PDL drug class with this indication. The Department of Human Services (DHS) is updating the guidelines to determine medical necessity of Antibiotics, Inhaled to ensure that use of these agents is consistent with indications that are medically accepted or included

*01-19-15	09-19-14	27-19-11	
02-19-10	11-19-10	30-19-10	
03-19-10	14-19-10	31-19-15	
08-19-16	24-19-12	32-19-10	33-19-14

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>.

in the FDA-approved package labeling. DHS also added language to ensure that these agents are used for beneficiaries of an appropriate age and with a dose and duration of therapy consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The revisions to the guidelines to determine medical necessity of Antibiotics, Inhaled were subject to public review and comment and subsequently approved for implementation by DHS.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Antibiotics, Inhaled are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Antibiotics, Inhaled) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II  
Antibiotics, Inhaled

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, Inhaled at: <https://papdl.com/preferred-drug-list>.
2. An Antibiotic, Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

**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 beneficiary:

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 beneficiary'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 the Quantity Limits Chapter.

NOTE: If the beneficiary 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 beneficiary, the request for prior authorization will be approved.

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 beneficiary.