Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 6, 2025	January 5, 2026	*See below

SUBJECT

Prior Authorization of Antibiotics, GI and Related Agents – Pharmacy Services

BY

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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: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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, GI and Related Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Antibiotics, GI and Related Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Antibiotics, GI and Related Agents to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Antibiotics, GI and Related Agents to remove the guidelines related to Xifaxan (rifaximin) and Zinplava (bezlotoxumab). Medicaid covers drugs approved by the U.S. Food

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02-26-02	11-26-02	30-26-02	
03-26-02	14-26-02	31-26-02	
08-26-02	24-26-02	32-26-02	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

and Drug Administration when the manufacturer participates in the Medicaid Drug Rebate Program (MDRP). The manufacturer of Xifaxan (rifaximin) is no longer participating in the MDRP. Xifaxan (rifaximin) is no longer a Medicaid covered drug. Zinplava (bezlotoxumab) was discontinued by the manufacturer in January 2025.

The revisions to the guidelines to determine medical necessity of prescriptions for Antibiotics, GI and Related Agents were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Antibiotics, GI and Related Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department 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, GI and Related Agents) 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 and products that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Antibiotics, GI and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, GI and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotics, GI and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, GI and Related Agents at: https://papdl.com/preferred-drug-list.

2. An Antibiotics, GI and Related Agent 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: https://www.pa.gov/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotics, GI and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antibiotics, GI and Related Agent for the treatment of 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 are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. For Dificid (fidaxomicin) for the treatment of *Clostridioides difficile* infection (CDI), **one** of the following:

    a. Has at least **one** of the following factors associated with a high risk for recurrence of CDI:

        i. Age ≥65 years,
        ii. Clinically severe CDI (as defined by a Zar score ≥2),
        iii. Is immunocompromised,

    b. Has a recurrent episode of CDI,

    c. Is prescribed Dificid (fidaxomicin) as a continuation of therapy upon inpatient discharge;

AND

5. For the treatment of travelers' diarrhea, has a history of therapeutic failure of or a contraindication or an intolerance to azithromycin; **AND**

6. For all other non-preferred Antibiotics, GI and Related Agents and for all other indications, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, GI and Related Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

7. If a prescription for an Antibiotics, GI and Related Agent is for 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.

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 Antibiotics, GI and Related Agent. 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.