

ISSUE DATE December 6, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Antibiotics, GI and Related Agents – Pharmacy Services		BY  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: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

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 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, GI and Related Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for

*01-19-99	09-19-95	27-19-94	33-19-96
02-19-93	11-19-92	30-19-91	
03-19-92	14-19-91	31-19-99	
08-19-102	24-19-94	32-19-91	

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
<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 13, 2019, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of Antibiotics, GI and Related Agents:

- Addition of guidelines that the beneficiary's diagnosis, age, and prescribed dose are consistent with FDA-approved labeling or medical literature;
- Revision to the guideline for Xifaxan (rifaximin) for traveler's diarrhea to require therapeutic failure, contraindication, or intolerance of azithromycin only; and
- Revision to the guidelines for irritable bowel syndrome with diarrhea (IBS-D) to include therapeutic failure, contraindication, or intolerance of loperamide and a bile acid sequestrant rather than loperamide and an antispasmodic prior to treatment with Xifaxan (rifaximin) to be consistent with national treatment guidelines for IBS-D.

The revisions to the guidelines to determine medical necessity of Antibiotics, GI and Related Agents, as recommended by the DUR Board, 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 that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

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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 Antibiotic, 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 Antibiotic, 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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, 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 Antibiotic, 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 is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. For Xifaxan (rifaximin), **one** of the following:
 - a. For the treatment of travelers' diarrhea, has a history of therapeutic failure, contraindication, or intolerance of azithromycin,
 - b. For the treatment of hepatic encephalopathy, has a history of therapeutic failure, contraindication, or intolerance of lactulose,
 - c. For the treatment of irritable bowel syndrome with diarrhea (IBS-D), **all** of the following:
 - i. Is prescribed the requested medication by or in consultation with a gastroenterologist,
 - ii. Had other etiologies for chronic diarrhea ruled out,

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- iii. Has a documented history of therapeutic failure of **both** of the following:
 - 1) Lactose, gluten, and artificial sweetener avoidance
 - 2) A low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet,
- iv. Has a documented history of therapeutic failure, contraindication, or intolerance of **both** of the following:
 - 1) Loperamide
 - 2) A bile acid sequestrant;

AND

- 5. For Zinplava (bezlotoxumab), **all** of the following:
 - a. Is prescribed Zinplava (bezlotoxumab) by or in consultation with a gastroenterologist or an infectious disease specialist,
 - b. Has a recent stool test positive for toxigenic *Clostridium difficile*,
 - c. Has at least **one** of the following factors associated with a high risk for recurrence of *Clostridium difficile* infection (CDI):
 - i. Age \geq 65 years,
 - ii. Extended use of one or more systemic antibacterial drugs,
 - iii. Clinically severe CDI (as defined by a Zar score \geq 2),
 - iv. At least one previous episode of CDI within the past 6 months or a documented history of at least two previous episodes of CDI,
 - v. Is immunocompromised,
 - vi. The presence of a hypervirulent strain of CDI bacteria (ribotypes 027, 078, or 244),
 - d. Is receiving Zinplava (bezlotoxumab) in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of CDI,
 - e. Has not received a prior course of treatment with Zinplava (bezlotoxumab),
 - f. Has documentation from the prescriber attesting that the benefit of therapy is expected to outweigh the risks if the beneficiary has a history of congestive heart failure;

AND

- 6. For all other non-preferred Antibiotics, GI and Related Agents, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antibiotics, GI and Related Agents;
AND

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

FOR RENEWALS OF PRIOR AUTHORIZATION FOR XIFAXAN (RIFAXIMIN): The determination of medical necessity of a request for renewal of a prior authorization for Xifaxan (rifaximin) for an indication of IBS-D that was previously approved will take into account whether the beneficiary:

1. Has documentation of a successful initial treatment course; **AND**
2. Has documented recurrence of IBS-D symptoms; **AND**
3. Has not received 3 treatment courses with Xifaxan (rifaximin) in the beneficiary's lifetime; **AND**
4. If a prescription for Xifaxan (rifaximin) 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.

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, 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.

D. Dose and Duration of Therapy

The Department of Human Services (Department) will limit authorization of prescriptions for Zinplava (bezlotoxumab) consistent with the FDA-approved package labeling.

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E. Automated Prior Authorization

Prior authorization of a prescription for Xifaxan 550 mg with a prescribed quantity that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 90 days prior to the date the prescription is presented to the pharmacy that includes a diagnosis of hepatic encephalopathy, thereby documenting that the guideline listed above for an indication of hepatic encephalopathy was met.

F. 5-Day Supply

The Department will cover a 5-day supply of the prescribed medication without prior authorization if, in the professional judgment of the dispensing pharmacist, the beneficiary has an immediate need for the medication, unless the dispensing pharmacist determines that taking the medication either alone or along with other medications that the beneficiary may be taking would jeopardize the health and safety of the beneficiary. The maximum number of 5-day supplies of a prescription for Xifaxan (rifaximin) that the Department will cover without prior authorization is one 5-day supply per beneficiary during a 6-month period.

G. References

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