



<b>ISSUE DATE</b> November 13, 2015	<b>EFFECTIVE DATE</b> October 26, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Antibiotics, GI - Pharmacy Service		<b>BY</b>   Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994). Please send in your application(s) as soon as possible.

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of Antibiotics, GI, including the type of medical information needed to evaluate requests for medical necessity.

**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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through

*01-15-36	09-15-34	27-15-28	
02-15-28	11-15-27	30-15-27	
03-15-28	14-15-29	31-15-35	
08-15-34	24-15-29	32-15-28	33-15-33

**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>

the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

**DISCUSSION:**

During the September 10, 2015 meeting, the DUR Board recommended updates to the guidelines to determine medical necessity of Antibiotics, GI to allow for an appropriate medical necessity determination of Xifaxan (rifaxamin) when prescribed for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults. The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Antibiotics, GI are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Antibiotics, GI 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 chapters related to Antibiotics, GI) 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, GI

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Antibiotics, GI**

A. Prescriptions That Require Prior Authorization

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

1. A prescription for a non-preferred Antibiotic, GI. See Preferred Drug List (PDL) for the list of preferred Antibiotics, GI at: [www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
2. A prescription for an Antibiotic, GI with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: [http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s\\_002077.pdf](http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf)

B. 5-Day Supply

A pharmacist may dispense a 5-day supply of the prescribed medication without prior authorization if, in the professional judgment of the pharmacist, the recipient has an immediate need for the medication, unless the pharmacist determines that taking the medication either alone or along with other medications that the recipient may be taking, would jeopardize the health and safety of the recipient. The maximum number of 5-day supplies of a prescription for Xifaxan (rifaximin) that can be dispensed without prior authorization is one (1) 5-day supply per recipient during a six (6) month period.

C. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Antibiotic, GI, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Flagyl ER, whether the recipient has a history of:
  - a. Therapeutic failure of preferred oral metronidazole or intravaginal gel (if applicable)OR
  - b. A contraindication to or intolerance of preferred metronidazole
2. For Xifaxan (rifaximin), whether the recipient has:

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a. A documented diagnosis of traveler's diarrhea

**AND**

b. A documented history of:

i. Therapeutic failure of at least one fluoroquinolone

**OR**

ii. A contraindication to or intolerance of fluoroquinolone therapy

**OR**

c. A documented diagnosis of hepatic encephalopathy

**AND**

d. A documented history of therapeutic failure, contraindication or intolerance to lactulose

**OR**

e. A documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

**AND**

f. A prescription written by, or in consultation with, a gastroenterologist

**AND**

g. Other etiologies for chronic diarrhea ruled out

**AND**

h. A documented therapeutic failure of lactose, gluten, and artificial sweetener avoidance and a low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet

**AND**

i. A documented history of therapeutic failure, contraindication or intolerance to loperamide and an antispasmodic

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FOR RENEWALS OF PRESCRIPITONS FOR XIFAXAN: The determination of medical necessity of requests for prior authorization for renewals of prescriptions for Xifaxan for an indication of irritable bowel syndrome with diarrhea (IBS-D) that were previously approved will take into account whether the recipient:

- a. Has documentation of a successful initial treatment course

**AND**

- b. Has documented recurrence of IBS-D symptoms

**AND**

- c. Has not received 3 treatment courses in their lifetime

- 3. For all other non-preferred GI Antibiotics, whether the recipient has a history of therapeutic failure, contraindication or intolerance of the preferred GI Antibiotics.
- 4. For a prescription for an Antibiotic, GI 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.

D . 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 the request for a prescription for an Antibiotic, GI. 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 recipient.

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 PROMISe Point-of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 90 days prior to the date of service that documents that the

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guidelines to determine medical necessity listed above for an indication of hepatic encephalopathy have been met

References

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