pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 12, 2018	December 17, 2018	*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: 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, 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 under 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' (DHS) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy,

*01-18-36	09-18-37	27-18-36	33-18-36
02-18-31	11-18-31	30-18-31	
03-18-32	14-18-32	31-18-37	
08-18-39	24-18-33	32-18-31	

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

safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

Centers for Disease Control and Prevention (CDC) and International Society of Travel Medicine (ISTM) recommend azithromycin and fluoroquinolones as appropriate first-line medications for the treatment of travelers' diarrhea when antibacterial therapy is indicated. Xifaxan is recommended as an alternative agent. During the September 25, 2018, DUR Board meeting, the DUR Board recommended that DHS update the medical necessity guidelines for Antibiotics, GI and Related Agents to align with CDC and ISTM recommendations. DHS also added language to ensure that the prescribed dose and duration of therapy of Xifaxan is consistent with Food and Drug Administration approved package labeling or nationally recognized medical compendia. The proposed changes to the medical necessity guidelines 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, GI and Related Agents 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, 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

SECTION II
Antibiotics, GI and Related Agents

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: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

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 beneficiary has an immediate need for the medication, unless the 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 can be dispensed without prior authorization is one (1) 5-day supply per beneficiary 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 and Related Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Xifaxan (rifaximin), whether the beneficiary:

   a. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling or nationally recognized compendia

   AND

   b. Has one of the following:

i. A documented diagnosis of travelers' diarrhea

AND

ii. A documented history of:

a. Therapeutic failure of azithromycin or at least one fluoroquinolone

OR

b. A contraindication to or intolerance of azithromycin and fluoroquinolone therapy

OR

iii. A documented diagnosis of hepatic encephalopathy

AND

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

OR

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

AND

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

AND

vii. Other etiologies for chronic diarrhea ruled out

AND

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

AND

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

AND

2. For Zinplava (bezlotoxumab), whether the beneficiary:

a. Is age-appropriate according to FDA-approved package labeling, compendia, or peer-reviewed medical literature

AND

b. Is being prescribed Zinplava (bezlotoxumab) by or in consultation with a gastroenterologist or an infectious disease specialist

AND

c. Has a recent stool test positive for toxigenic *Clostridium difficile*

AND

d. Has at least one of the following factors associated with a high risk for recurrence of *Clostridium difficile* infection (CDI):

i. Age ≥65 years
ii. Extended use of one or more systemic antibacterial drugs
iii. Clinically severe CDI (as defined by a Zar score ≥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)

AND

e. Is receiving Zinplava (bezlotoxumab) in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of CDI

AND

f. Has not received a prior course of treatment with Zinplava (bezlotoxumab)

AND

g. If has a history of congestive heart failure, has documentation from the prescriber attesting that the benefit of therapy is expected to outweigh the risks

AND

3. For all other non-preferred Antibiotics, GI and Related Agents, whether the beneficiary has a history of therapeutic failure, contraindication, or intolerance of the preferred Antibiotics, GI and Related Agents

AND

4. 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 PRESCRIPITONS FOR XIFAXAN: The determination of medical necessity of requests for prior authorization for renewal of a prescriptions for Xifaxan for an indication of irritable bowel syndrome with diarrhea (IBS-D) that were 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 in their lifetime.

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.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above to assess the medical necessity of a prescription for an Antibiotic, GI and Related Agent. If the guidelines in Section C. 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.

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 DHS will be automatically approved when DHS' Point-of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 90 days of 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. Dose and Duration of Therapy

DHS will limit authorization of prescriptions for Zinplava (bezlotoxumab) consistent with the FDA-approved package labeling.

G. References

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