pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 2, 2021	January 3, 2022	*See below

SUBJECT

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

BY

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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. The guidelines to determine the medical necessity of Antibiotics, GI and Related Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Antibiotics, GI and Related Agents to the appropriate MCO.

BACKGROUND:

*01-21-15	09-21-14	27-21-05	33-21-14
02-21-02	11-21-04	30-21-09	
03-21-02	14-21-05	31-21-17	
08-21-16	24-21-12	32-21-02	

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

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Antibiotics, GI and Related Agents:

- Removal of the guidelines specific to Xifaxan (rifaximin);
- Revision of the guidelines for the treatment of travelers' diarrhea, irritable bowel syndrome with diarrhea (IBS-D), and hepatic encephalopathy to apply to all drugs in this class with these indications;
- Revision to the guidelines for the treatment of IBS-D to reflect updated consensus treatment guidelines;
- Addition of guidelines for the use of Dificid (fidaxomicin) for the treatment of *Clostridioides difficile* infection; and
- Removal of the guideline for Zinplava (bezlotoxumab) that the beneficiary 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.

The revisions to the guidelines to determine medical necessity of prescriptions for Antibiotics, GI and Related Agents submitted for prior authorization, as recommended by the P&T Committee, 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 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, contraindication, or intolerance of azithromycin; **AND**

6. For the treatment of hepatic encephalopathy, has a history of therapeutic failure, contraindication, or intolerance of lactulose; **AND**

7. For the treatment of irritable bowel syndrome with diarrhea (IBS-D), **both** of the following:

   a. Is prescribed the requested medication by or in consultation with a gastroenterologist
   b. Has a history of therapeutic failure of a low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet;

   AND

8. 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 *Clostridioides difficile,*

   c. Has at least **one** of the following factors associated with a high risk for recurrence of 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),

   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);

   AND

9. 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 approved or medically accepted for the beneficiary's diagnosis;
   AND

10. 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 AN ANTIBIOTIC, GI AND RELATED AGENT FOR AN INDICATION OF IBS-D: The determination of medical necessity of a request for renewal of a prior authorization for an Antibiotic, GI and Related Agent 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. For Xifaxan (rifaximin), has not received 3 treatment courses in the beneficiary's lifetime; **AND**

4. If a prescription for an Antibiotics, 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.

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

Requests for prior authorization of Zinplava (bezlotoxumab) and Xifaxan (rifaximin) will be approved for a dose and duration of therapy consistent with FDA-approved package labeling.

E. 5-Day Supply

The Department of Human Services 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.

F. References

1. Flagyl ER [package insert]. New York, NY; Pfizer; August 2006.
2. Hill DR, Ericsson CD, Pearson RD, et al. The practice of travel medicine: guidelines by the Infectious Diseases Society of America. *Clin Infect Dis*. 2006;43:1499-539.
3. Xifaxan [package insert]. Bridgewater, NJ; Salix Pharmaceutical, Inc. October 2020.
4. American Gastroenterological Association Institute Guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology 2014;147:1146–1148.
5. Zinplava [package insert]. Whitehouse Station, NJ; Merck & Co., Inc.; October 2016.
6. Kelly CP, Lamont JT. Clostridium difficile in adults: treatment. UpToDate. Accessed July 21, 2021.
7. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. J Travel Med. 2017;24(suppl 1):S57-S74.
8. Centers for Disease Control and Prevention. Travelers' diarrhea. https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/travelers-diarrhea. Revised November 22, 2019. Accessed July 20, 2021.
9. LaRocque R, Harris JB. Travelers' diarrhea: clinical manifestations, diagnosis, and treatment. Calderwood SB, Bloom A, eds. Waltham, MA: UpToDate. Revised July 12, 2021. Accessed July 20, 2021.
10. Wald A. Treatment of irritable bowel syndrome in adults. Talley NJ, Grover S, eds. Waltham, MA: UpToDate Inc. Updated July 15, 2020. Accessed July 20, 2021.
11. Lacy, BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J.Gastroenterol. 2021;116:17-44.
12. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by AASLD and EASL. https://www.aasld.org/sites/default/files/2019-06/141022_AASLD_Guideline_Encephalopathy_4UFd_2015.pdf. Accessed July 20, 2021.