Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2021**
Policy Number: PHW.PDL.115	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
Policy Name: Antibiotics, GI and Related Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2022: policy revised according to DHS revisions effective 01/03/2022

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Antibiotics, GI and Related Agents

Reference Number: PHW.PDL.115
Effective Date: 01/01/2020
Last Review Date: 10/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that GI and Related Antibiotic Agents are **medically necessary** when the following criteria are met:

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.

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 member:

1. Is prescribed an 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 *Clostridioides 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),

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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 irritable bowel syndrome with diarrhea (IBS-D) that was previously approved will take into account whether the member:

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 member'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 PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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 member.

D. **Dose and Duration of Therapy**:

For Zinplava (bezlotoxumab) and Xifaxan (Rifaximin) approved for a dose and duration of therapy consistent with FDA-approved package labeling.

For all other requests, duration of request or 6 months (whichever is less)

E. 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.aasid.org/sites/default/files/2019-06/141022_AASLD_Guideline_Encephalopathy_4UFd_2015.pdf. Accessed July 20, 2021.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021