

Clinical Policy: Antibiotics, GI and Related Agents

Reference Number: PHW.PDL.115

Effective Date: 01/01/2020

Last Review Date: 11/2024

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 PA Health & 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.
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 Difid (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 \geq 65 years,
 - ii. Clinically severe CDI (as defined by a Zar score \geq 2),
 - iii. Is immunocompromised,
- b. Has a recurrent episode of CDI,
- c. Is prescribed Difacid (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), or small intestinal bacterial overgrowth (SIBO), is prescribed the requested medication by or in consultation with a gastroenterologist;

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 \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);

AND

- 9. For all other non-preferred Antibiotics, GI and Related Agents, has a history of therapeutic failure of or a contraindication or an intolerance of the preferred Antibiotics, GI and Related Agents approved or medically accepted for the member'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 OR SIBO: 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 OR SIBO that was previously approved will take into account whether the member:

- 1. For IBS-D, **all** of the following:
 - a. Has documentation of a successful initial treatment course,
 - b. Has documented recurrence of IBS-D symptoms,
 - c. Is prescribed the requested medication by or in consultation with a gastroenterologist,
 - d. For Xifaxan (rifaximin), has not received 3 treatment courses in the member's lifetime;

AND

- 2. For SIBO, is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**
- 3. 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, nationally recognized compendia, or peer-reviewed medical literature.

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

E. References

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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.
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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.
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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.

CLINICAL POLICY

Antibiotics, GI and Related Agents



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13. Pimentel M, Saad R, Long M, and Rao S. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *Am J Gastroenterol*. 2020; 115(2): 165-178.
14. Quigley E, Murray J, and Pimentel M. AGA Clinical Practice Update on Small Intestinal Bacterial Overgrowth: Expert Review. *Gastroenterology*. 2020;159:1526-1532.

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
Q1 2023 annual review: no changes.	11/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023
Q1 2025 annual review: no changes.	11/2024