

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
ANTIBIOTICS, GI AND RELATED AGENTS

Proposed Effective Date: October 1, 2025

Revisions are noted with a ~~striketrough~~ for deletions and **bold and underline** for additions.

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 Antibiotics, 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 Antibiotics, 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.pa.gov/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotics, GI and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **For Xifaxan (rifaximin), see Section D. Xifaxan (rifaximin).**
2. Is prescribed the Antibiotics, 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**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. For Difcid (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,

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- ii. Clinically severe CDI (as defined by a Zar score ≥ 2),
- iii. Is immunocompromised,

b. Has a recurrent episode of CDI,

c. Is prescribed Difidid (fidaxomicin) as a continuation of therapy upon inpatient discharge;

AND

6. For the treatment of travelers' diarrhea, has a history of therapeutic failure of or a contraindication or an intolerance to azithromycin; **AND**
7. ~~For the treatment of hepatic encephalopathy, has a history of therapeutic failure of or a contraindication or an intolerance to lactulose; **AND**~~
8. ~~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**~~
9. 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

10. For all other non-preferred Antibiotics, GI and Related Agents and for all other indications, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred

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Antibiotics, GI and Related Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

11. If a prescription for an Antibiotics, GI and Related Agent is for 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 ANTIBIOTICS, 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 Antibiotics, GI and Related Agent for an indication of IBS-D or SIBO that was previously approved will take into account whether the beneficiary:~~

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 beneficiary'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 for 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 Antibiotics, 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

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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, nationally recognized compendia, or peer-reviewed medical literature.~~

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.~~

D. Xifaxan (rifaximin)

Requests for Xifaxan (rifaximin) will only be approved if all of the following conditions are met:

1. **The request is for Xifaxan (rifaximin) 200 mg tablet.**
2. **The requested dose and duration of therapy are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.**
3. **The request is for the treatment of hepatic encephalopathy.**
4. **The beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to lactulose.**

Xifaxan is not covered for other indications. Any strengths or formulations of Xifaxan (rifaximin) other than Xifaxan (rifaximin) 200 mg tablet are not covered.