Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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:

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.

B. 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. 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**

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 are 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 of or a contraindication or an intolerance to azithromycin; **AND**

6. For the treatment of hepatic encephalopathy, has a history of therapeutic failure of or a contraindication or an intolerance to 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 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 and for all other indications, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, GI and Related Agents approved or medically accepted for the beneficiary's diagnosis.

   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.

   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 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.

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ANTIBIOTICS, GI and RELATED AGENTS PRIOR AUTHORIZATION FORM *(form effective 1/8/2024)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/State/Zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:	
Dose/directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

INITIAL requests

1. For treatment of HEPATIC ENCEPHALOPATHY:
☐Has a history of trial and failure of or a contraindication or an intolerance to lactulose

2. For treatment of TRAVELERS' DIARRHEA:
☐Has a history of trial and failure of or a contraindication or an intolerance to azithromycin

3. For treatment of IRRITABLE BOWEL SYNDROME WITH DIARRHEA:
☐Requested medication is prescribed by or in consultation with a gastroenterologist

4. For treatment of SMALL INTENSTINAL BACTERIAL OVERGROWTH:
☐Requested medication is prescribed by or in consultation with a gastroenterologist

5. For DIFICID (FIDAXOMICIN) for treatment of *CLOSTRIDIOIDES DIFFICILE* INFECTION*:*
☐Has at least one of the following risk factors associated with a high risk of recurrence of *Clostridioides difficile* infection:
- ☐65 years of age or older
- ☐Clinically severe *Clostridioides difficile* infection (Zar score ≥2)
- ☐Immunocompromised status

☐Has a recurrent episode of *Clostridioides difficile* infection
☐Is prescribed Dificid (fidaxomicin) as a continuation of therapy upon inpatient discharge

6. For ZINPLAVA (BEZLOTOXUMAB):
Beneficiary's weight (in kg): _____ kg
☐Requested medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist
☐Has a recent stool test that is positive for toxigenic *Clostridioides difficile*

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- ☐ Has at least one of the following factors associated with a high risk of recurrence of *Clostridioides difficile* infection:
  - ☐ 65 years of age or older
  - ☐ Extended use of one or more systemic antibacterial drugs
  - ☐ Clinically severe *Clostridioides difficile* infection
  - ☐ At least one previous episode of *Clostridioides difficile* infection within the past six months
  - ☐ Documented history of at least two previous episodes of *Clostridioides difficile* infection
  - ☐ Immunocompromised status
  - ☐ Infected with a hypervirulent strain of *Clostridioides difficile* (ribotypes 027, 078, or 244)
- ☐ Will receive Zinplava (bezlotoxumab) in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of *Clostridioides difficile* infection
- ☐ Has not received a prior course of treatment with Zinplava (bezlotoxumab)

7. For ALL OTHER NON-PREFERRED Antibiotics, GI and Related Agents and for ALL OTHER INDICATIONS:

- ☐ Has a history of trial and failure of or a contraindication or an intolerance to the preferred Antibiotics, GI and Related Agents that are approved or medically accepted for the treatment of the beneficiary's diagnosis

RENEWAL requests

1. For treatment of IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D):

- ☐ Had a successful initial treatment course
- ☐ Is experiencing recurrence of IBS-D symptoms
- ☐ Requested medication is prescribed by or in consultation with a gastroenterologist
- ☐ **Request is for XIFAXAN (RIFAXIMIN) and:**
  - ☐ Has not received 3 or more treatment courses of Xifaxan (rifaximin) in the beneficiary's lifetime

2. For treatment of SMALL INTESTINAL BACTERIAL OVERGROWTH:

- ☐ Requested medication is prescribed by or in consultation with a gastroenterologist

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**:

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