Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

ANTIBIOTICS, GI AND RELATED AGENTS

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.

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 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 Xifaxan (rifaximin), **one** of the following:

    a. For the treatment of travelers' diarrhea: has a history of therapeutic failure, contraindication, or intolerance to azithromycin,

    b. For the treatment of hepatic encephalopathy, has a history of therapeutic failure, contraindication, or intolerance to lactulose,

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

        i. Is prescribed the requested medication by or in consultation with a gastroenterologist,

        ii. Has had other etiologies for chronic diarrhea ruled out,

        iii. Has a documented history of therapeutic failure of **both** of the following:

            1) Lactose, gluten, and artificial sweetener avoidance
            2) A low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet,

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iv. Has a documented history of therapeutic failure, contraindication, or intolerance of **both** of the following:

1) Loperamide
2) A bile acid sequestrant;

AND

5. 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 *Clostridium difficile,*

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

f. 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;

AND

6. 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;

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.

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FOR RENEWALS OF PRIOR AUTHORIZATION FOR XIFAXAN (RIFAXIMIN): The determination of medical necessity of a request for renewal of a prior authorization for Xifaxan (rifaximin) for an indication of irritable bowel syndrome with diarrhea (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. Has not received 3 treatment courses with Xifaxan (rifaximin) in the beneficiary's lifetime

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

Authorization of prescriptions for Zinplava (bezlotoxumab) will be consistent with the FDA-approved package labeling.

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XIFAXAN (rifaximin) PRIOR AUTHORIZATION FORM

☐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:		Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Product requested: Xifaxan tablet	Strength: ☐200 mg ☐550 mg ☐ _____		
Dose/directions: ☐200 mg three times daily x 3 days ☐550 mg three times daily x 14 days ☐550 mg twice daily ☐other: _____		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

INITIAL requests - complete questions applicable to beneficiary's diagnosis		
Hepatic encephalopathy: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of lactulose?	☐Yes ☐No	*Submit documentation.*
Travelers' diarrhea: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of azithromycin (Zithromax)?	☐Yes ☐No	*Submit documentation of all medications tried and outcomes.*
Irritable bowel syndrome with diarrhea (IBS-D): Is Xifaxan being prescribed by, or in consultation with, a gastroenterologist?	☐Yes ☐No	*Submit documentation of consultation, if applicable.*
IBS-D: Have other causes of chronic diarrhea been ruled out, such as inflammatory bowel disease, malabsorption syndromes, chronic infection, celiac disease, malignancy, etc.?	☐Yes ☐No	*Submit documentation of differential diagnosis.*
IBS-D: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of the following medications? *Check all that apply.* ☐antispasmodics (e.g., dicyclomine) ☐bile acid sequestrants (e.g., cholestyramine)	☐Yes ☐No	*Submit documentation of all medications tried and outcomes.*
IBS-D: Did the beneficiary try and fail standard IBS-D dietary modifications (e.g., avoidance of lactose, gluten, and artificial sweeteners; low FODMAP diet)?	☐Yes ☐No	*Submit documentation of dietary changes tried and outcomes.*
All other diagnoses: Submit medical literature supporting the use of Xifaxan for the beneficiary's diagnosis and all treatment regimens tried.		
RENEWAL requests		
Irritable bowel syndrome with diarrhea (IBS-D): Was the beneficiary's previous treatment course with Xifaxan successful?	☐Yes ☐No	*Submit documentation of clinical response.*
IBS-D: Have the beneficiary's symptoms of IBS-D recurred since the previous treatment course?	☐Yes ☐No	*Submit documentation.*
IBS-D: How many treatment courses of Xifaxan has the beneficiary had? *Submit documentation.*	☐one ☐two ☐other: _____	

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

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ZINPLAVA (bezlotoxumab) PRIOR AUTHORIZATION FORM

PRIOR AUTHORIZATION INFORMATION		PRESCRIBER INFORMATION	
☐New request ☐Renewal request	Total # of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		State license #:	
LTC facility contact/phone:		NPI:	MA Provider ID#:
BENEFICIARY INFORMATION		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Medication requested: ☐Zinplava 1000 mg/40 ml injection vial		Quantity: _____ vials
Dose/directions:		Weight: _____ lbs / kg
Diagnosis *(submit documentation)*:		Dx codes (*required*):
Zinplava is part of the DHS Specialty Pharmacy Drug Program and is only available from of one of the two DHS specialty pharmacies – Walgreen's Specialty Pharmacy.		
1. Is Zinplava being prescribed by, or in consultation with, a gastroenterologist or an infectious disease specialist?	☐Yes ☐No	*If prescriber is not a gastroenterologist or infectious disease specialist, submit documentation of consultation.*
2. Does the beneficiary have a recent stool test that is positive for toxigenic *Clostridium difficile*?	☐Yes ☐No	*Submit documentation.*
3. Does the beneficiary have any of the following risk factors associated with a high risk of recurrence of *Clostridium difficile* infection? ☐65 years of age or older ☐extended use of one or more systemic antibacterial drugs ☐clinically severe *Clostridium difficile* infection ☐at least one previous episode of *Clostridium difficile* infection within the past 6 months ☐documented history of at least two previous episodes of *Clostridium difficile* infection ☐immunocompromised status ☐infected with a hypervirulent strain of *Clostridium difficile* (ribotypes 027, 078, or 244)	☐Yes ☐No	*Submit documentation.*
4. Will the beneficiary receive Zinplava in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of *Clostridium difficile* infection (eg., metronidazole, vancomycin, or fidaxomicin)?	☐Yes ☐No	*Submit documentation of antibiotic treatment regimen.*
5. Did the beneficiary ever receive Zinplava in the past?	☐Yes – *Submit documentation supporting the use of more than 1 course of treatment with Zinplava.* ☐No	
6. Does the beneficiary have a history of congestive heart failure?	☐Yes – *Submit documentation attesting that the benefits of treatment with Zinplava is expected to outweigh the risks.* ☐No	

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Prescriber Signature:	Date: