

All requests for Xifaxan (rifaximin) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Xifaxan (rifaximin) Prior Authorization Criteria:

For all requests for Xifaxan (rifaximin) all of the following criteria must be met:

- The requested medication is prescribed by or in consultation with a gastroenterology specialist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of Traveler's Diarrhea and the following criteria is met:

- Member must have a diagnosis of traveler's diarrhea caused by non-invasive strains of *Escherichia coli*; not to be used with diarrhea complicated by fever or bloody stools
- Member must have a history of trial and failure, contraindication, or intolerance to either a fluoroquinolone (e.g. ciprofloxacin or levofloxacin) or azithromycin
- **Initial Duration of Approval:** 3 days
- **Reauthorization criteria**
 - Member must be reevaluated for preauthorization and will only be eligible for 1 3-day course per 30 days

Coverage may be provided with a diagnosis of Hepatic Encephalopathy and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance of at least 2 days of treatment with non-absorbable disaccharides (e.g. lactulose, lactitol)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
 - Clinical documentation of improvement in member's mental status.
- **Reauthorization Duration of Approval:** 6 months

Coverage may be provided with a diagnosis of Irritable Bowel Syndrome (IBS) with diarrhea and the following criteria is met:

- Member must have failed dietary modifications [e.g. lactose restricted diet, if lactose intolerant; exclusion of gas-producing foods; low carbohydrate diet, and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs)].
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
 - Antidiarrheal agents (such as loperamide)

- A bile acid sequestrant (e.g. cholestyramine)
- Antispasmodic agents (e.g. dicyclomine) or a tricyclic antidepressant (e.g. amitriptyline)
- **Initial Duration of Approval:** 14 days
- **Reauthorization criteria**
 - There must be documented, significant improvement with prior courses of treatment.
 - Member will have a limit of three 14-day course treatments. Member must wait 1 full month before being reevaluated for preauthorization.
- **Reauthorization Duration of Approval:** 14 days

Coverage may be provided with a diagnosis of small intestinal bacterial overgrowth (SIBO) and the following criteria is met:

- Documentation of one of the following:
 - Endoscopic culture with $>10^3$ bacteria colony forming units/mL
 - Positive lactulose or glucose breath test with hydrogen increase of ≥ 20 ppm above baseline within 90 minutes
 - Positive lactulose or glucose breath test for methane (≥ 10 ppm at any point during testing)
- Member must have a history of trial and failure, contraindication, or intolerance to two systemic antibiotics:
 - Amoxicillin / Clavulanic Acid
 - Ciprofloxacin
 - Doxycycline
 - Metronidazole
 - Neomycin
 - Sulfamethoxazole / Trimethoprim
 - Tetracycline
- For methane-predominant bacterial overgrowth, must be used in combination with neomycin.
- **Initial Duration of Approval:** 14 days
- **Reauthorization criteria**
 - There must be documented, significant improvement with prior courses of treatment.
 - Member will have a limit of **one** 14-day course treatments in the last 90 days.
- **Reauthorization Duration of Approval:** 14 days

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the



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branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

**XIFAXAN (RIFAXIMIN)
PRIOR AUTHORIZATION FORM- Page 1**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm**

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No		Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No		

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: _____ ICD Code: _____

For Traveler's Diarrhea:
Does the member have a diagnosis of traveler's diarrhea caused by non-invasive strains of Escherichia coli?
 Yes No
Does the member have diarrhea complicated by fever or bloody stools? Yes No

For Hepatic Encephalopathy:
Does the member have a history of trial and failure, contraindication, or intolerance of at least 2 days of treatment with nonabsorbable disaccharides (i.e. lactulose, lactitol)? Yes No

For Irritable Bowel Syndrome (IBS) with diarrhea:
Has the member failed dietary modifications [e.g. lactose restricted diet, if lactose intolerant; exclusion of gas-producing foods; low carbohydrate diet, and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs)]? Yes No
Does the member have a history of trial and failure, contraindication, or intolerance to any of the following: (Please check all that apply):

- Loperamide Yes No
- A bile acid sequestrant (e.g. cholestyramine) Yes No
- Antispasmodic agents (e.g. dicyclomine) OR a tricyclic antidepressants (e.g. amitriptyline) Yes No

For Small intestinal bacterial overgrowth (SIBO)
Does the member have documentation of one of the following? Please check which is applicable.

Endoscopic culture with >10³ bacteria colony forming units/mL.

Positive lactulose or glucose breath test with hydrogen increase of ≥ 20 ppm above baseline within 90 minutes.

Positive lactulose or glucose breath test for methane (≥10 ppm at any point during testing).

**XIFAXAN (RIFAXIMIN)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8 am to 7 pm**

MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

MEDICAL HISTORY (Complete for ALL requests)

For Small intestinal bacterial overgrowth (SIBO) continued:

Does the member have a history of trial and failure, contraindication, or intolerance to two systemic antibiotics?

Yes, please list in previous therapies box No

Does the member have methane-predominant bacterial overgrowth? Yes No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? Yes No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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