Updated: 05/2019
PARP Approved: 06/2019

Prior Authorization Criteria

Xifaxan

All requests for Xifaxan) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

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

- Medication strength must be Xifaxan 200mg tablet
- Member is 12 years of age or older
- Member must have diagnosis of traveler's diarrhea caused by non-invasive strains of *Escherichia coli*
- Member must have a history of trial and failure, contraindication, or intolerance to a 3-day course of twice daily ciprofloxacin OR azithromycin.
- Member must not have diarrhea complicated by fever or bloody stools
- **Initial Duration of Approval:** 3-day course of therapy (9 tablets) of the 200 mg tablets in any 30-day period.
- **Reauthorization criteria**
    - Member must be reevaluated for preauthorization

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

- Medication strength must be Xifaxan 550mg tablet
- Member is 18 years of age or older
- Member must have a history of trial and failure, contraindication, or intolerance of at least 2 days of treatment with nonabsorbable disaccharides (i.e. 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:

- Medication strength must be Xifaxan 550mg tablet
- Member is 18 years of age or older
- 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:
    - Two-week trial of antispasmodic agents (e.g. dicyclomine)
    - Six-week trial of Tricyclic antidepressants (e.g. amitriptyline, imipramine)
- **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 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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XIFAXAN
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Which of the following diagnoses will the medication be used for:
   a. Traveler's Diarrhea ☐ Yes ☐ No
      If yes, please answer questions below:
      i. Is the strength being prescribed Xifaxan 200mg? ☐ Yes ☐ No
      ii. Is member 12 years of age or older? ☐ Yes ☐ No
      iii. Does member have diagnosis of traveler's diarrhea caused by non-invasive strains of *Escherichia coli?* ☐ Yes ☐ No
      iv. Does member must have diarrhea complicated by fever or bloody stools? ☐ Yes ☐ No
   b. Hepatic Encephalopathy ☐ Yes ☐ No
      If yes, please answer questions below:
      i. Is strength being prescribed Xifaxan 550mg tablet? ☐ Yes ☐ No
      ii. Is member 18 years of age or older? ☐ Yes ☐ No
      iii. Does 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

c. Irritable Bowel Syndrome (IBS) with diarrhea ☐ Yes ☐ No
If yes, please answer questions below:
   i. Is strength being prescribed Xifaxan 550mg tablet? ☐ Yes ☐ No
   ii. Is member 18 years of age or older? ☐ Yes ☐ No
   iii. Has 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
   iv. Does member have a history of trial and failure, contraindication, or intolerance to any of the following: (Please check all that apply):
      1. Two-week trial of antispasmodic agents (e.g. dicyclomine, hyoscyamine) ☐ Yes ☐ No
      2. Six-week trial of Tricyclic antidepressants (e.g. amitriptyline, imipramine) ☐ Yes ☐ No

d. Other Diagnosis: _____

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

1. Which of the following diagnoses is the member using the medication for?
   a. Hepatic Encephalopathy
   ☐ Yes ☐ No

   If yes, answer the following questions
      i. Is there clinical documentation of improvement in member's mental status?
      ☐ Yes ☐ No

   b. Irritable Bowel Syndrome (IBS) with diarrhea
   ☐ Yes ☐ No
      i. Has the member experienced a significant improvement with treatment?
      ☐ Yes ☐ No

      ii. Please describe

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date