

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Xifaxan (rifaximin)

Override(s)
Prior Authorization
Quantity Limit

Diagnosis	Strength	Approval Duration
Hepatic Encephalopathy	550mg tablets	1 Year
Travelers' Diarrhea	200mg tablets	1 Time <i>Only</i>
Irritable bowel syndrome with diarrhea (IBS-D)	550mg tablets	Individual may have three 14 day courses of therapy within a 252 day time frame.

Medication	Strength	Quantity Limits
Xifaxan (rifaximin)	200mg tablets	9 tabs/30 days
Xifaxan (rifaximin)	550mg tablets	42 tablets per fill; 3 fills per 36 weeks*

***If Xifaxan (rifaximin) is being requested for prevention of overt hepatic encephalopathy recurrence, 2 tablets per day may be approved with no limits on number of fills.**

APPROVAL CRITERIA

Requests for Xifaxan (rifaximin) may be approved for patients who meet the following criteria:

- I. For Travelers' Diarrhea
 - A. Individual has a diagnosis of travelers' diarrhea (TD) ; **AND**
 - B. Individual has already been started on Xifaxan (rifaximin) and needs to complete treatment; **OR**
 - C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following agents (1. **or** 2. below) or has a contraindications to all of the following agents (both 1. **and** 2. below) (CDC, 2020):
 1. Generic Fluoroquinolone (ciprofloxacin or levofloxacin);
 2. Generic Azithromycin.

Note: Xifaxan (rifaximin) 200mg tablets are the only strength indicated for the treatment of travelers' diarrhea.

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OR

II. For Hepatic Encephalopathy

- A. Using to reduce the risk of overt hepatic encephalopathy (HE) recurrence; **AND**
- B. The individual is 18 years of age or older; **AND**
- C. The individual has had a trial and inadequate response or intolerance to or has a contraindication lactulose (AASLD, 2014);

Note: Xifaxan (rifaximin) 550mg tablets are the only recommended strength indicated for the treatment of Hepatic Encephalopathy. Xifaxan (rifaximin) 550mg tablets are not indicated for travelers' diarrhea.

OR

III. For Irritable Bowel Syndrome with diarrhea

- A. Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D); **AND**
- B. Individual is 18 years of age or older; **AND**
- C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following medications or has a contraindication to all of the following medications:
 - 1. Loperamide; **OR**
 - 2. Antispasmodics (hyoscyamine, dicyclomine); **OR**
 - 3. Tricyclic antidepressants (AGA 2014).

Note: Xifaxan (rifaximin) 550mg tablets are the only recommended strength indicated for the treatment of IBS-D.

OR

IV. For Small Intestinal Bacterial Overgrowth (SIBO)

- A. Individual is using for the treatment of small intestinal bacterial overgrowth; **AND**
- B. Individual is 18 years of age or older.

Note: Xifaxan (rifaximin) 550mg tablets are the only recommended strength indicated for the treatment of SIBO.

Key References:

1. Centers for Disease Control (CDC). Yellow Book 2020 – Health Information for International Travel. Chapter 2. Travelers' Diarrhea. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/travelers-diarrhea>. Last Updated: June 24, 2019. Accessed: September 20, 2019.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 19, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Ford AC, Moayyedi P, Chey WD; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2018.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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6. Lauritano EC, Gabrielli M, Scarpellini E, et. al. Antibiotic therapy in small intestinal bacterial overgrowth: rifaximin versus metronidazole. *Eur Rev Med Pharmacol Sci.* 2009; 13(2): 111-6.
7. Chang L, Lembo A, Sultan S. American Gastroenterological Association Institute Technical Review on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology.* 2014; 147(5):1149–1172. Available from: [http://www.gastrojournal.org/article/S0016-5085\(14\)01090-7/pdf](http://www.gastrojournal.org/article/S0016-5085(14)01090-7/pdf). Accessed on: March 1, 2015.
8. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. *Hepatology.* 2014;60(2):715-35.
9. Weinberg DS, Smalley W, Heidelbaugh JJ, et. al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology.* 2014; 147(5):1146-48.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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