

Xifaxan (rifaximin)

Override(s)
Prior Authorization
Quantity Limit

Diagnosis	Strength	Approval Duration
Hepatic Encephalopathy	550mg tablets	1 year
Travelers' Diarrhea	200mg tablets	1 month
Irritable bowel syndrome with diarrhea (IBS-D)	550mg tablets	1 year
Small Intestinal Bacterial Overgrowth (SIBO)	200mg, 550mg tablets	1 year

Medication	Strength	Quantity Limits
Xifaxan (rifaximin)	200mg tablets	9 tabs; 1 fill per 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.**

****If Xifaxan (rifaximin) 200 mg is being requested for the treatment of small intestinal bacterial overgrowth, 112 tablets may be approved per fill; 3 fills per 36 weeks.**

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, levofloxacin, or ofloxacin);
 2. Generic Azithromycin;

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

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 to lactulose (AASLD, 2014);

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

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;

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 (ACG 2020); **AND**
 - B. Individual is 18 years of age or older.

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: November 22, 2019. Accessed: September 10, 2022.
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 10, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Pimentel M, Saad RJ, Long MD, Rao SSC. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *Am J Gastroenterol*. 2020;115(2):165-178.
6. 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: June 6, 2019.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
8. 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. Jun;113(Suppl 2):1-18.

9. Lacy BE, Pimentel M, Brenner DM, et al; ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021 Jan 1;116:17-44.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
11. Pimentel M, Saad RJ, Long MD, Rao SSC. ACG clinical guideline: small intestinal bacterial overgrowth. *Am J Gastroenterol*. 2020;115(2):165-178.
12. 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.
13. 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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