

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

XIFAXAN 200 MG ONLY
(rifaximin)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xifaxan and other antibacterial drugs, Xifaxan when used to treat infection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Travelers' Diarrhea

Xifaxan is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults and pediatric patients 12 years of age and older.

Limitations of Use

Xifaxan should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*.

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Drug	1 Month Limit*	3 Month Limit*
Xifaxan 200 mg (rifaximin)	9 tablets / 25 days	Does Not Apply*

*The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

* These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of moderate to severe travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli*
AND
 - The patient is 12 years of age or older**AND**

Xifaxan 200mg Limit, Post PA Policy 3123-HJ UDR 04-2024.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428N 021423

- The infection is proven or strongly suspected to be caused by susceptible bacteria based on culture and susceptibility information OR local epidemiology and susceptibility patterns

AND

- The patient requires additional quantities due to multiple occurrences of travelers' diarrhea (TD) in a one-month period [Note: If diarrhea worsens or persists for more than 24-48 hours after initiating rifaximin, the drug should be discontinued and an alternative anti-infective considered.]

Quantity Limits apply.

POST LIMIT QUANTITY

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
Xifaxan 200 mg (rifaximin)	18 tablets / 25 days	Does Not Apply*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

*** These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.**

REFERENCES

1. Xifaxan [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; October 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed February 28, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/28/2024).
4. Centers for Disease Control and Prevention. CDC Yellow Book 2024: Health Information for International Travel. New York: Oxford University Press; 2023. Chapter 2, Preparing International Travelers.

Xifaxan 200mg Limit, Post PA Policy 3123-HJ UDR 04-2024.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428N 021423