

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**XIFAXAN 550MG ONLY**  
(rifaximin)

**Status: CVS Caremark Criteria**  
**Type: Initial 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.

#### Hepatic Encephalopathy

Xifaxan is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

In the trials of Xifaxan for HE, 91% of the patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed.

Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) scores > 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction.

#### Irritable Bowel Syndrome with Diarrhea

Xifaxan is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

### COVERAGE CRITERIA

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

- The requested drug is being prescribed to reduce the risk of overt hepatic encephalopathy (HE) recurrence
- OR**
- The patient has the diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

**AND**

- If the patient has previously received treatment with the requested drug, the patient is experiencing a recurrence of symptoms AND
- The patient has not already received an initial 14-day course of treatment AND two additional 14-day courses of treatment with the requested drug

### REFERENCES

1. Xifaxan [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc; January 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed March 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed March 2019.