

## PRIOR AUTHORIZATION CRITERIA

<b>BRAND NAME</b> (generic)	<b>XIFAXAN 550MG ONLY</b> (rifaximin)
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**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

Xifaxan will be covered with prior authorization when the following criteria are met:

- Xifaxan is being prescribed to reduce the risk of overt hepatic encephalopathy recurrence  
**OR**
- The patient has the diagnosis of irritable bowel syndrome with diarrhea

### REFERENCES

1. Xifaxan [package insert]. Raleigh, North Carolina: Salix Pharmaceuticals, Inc; May 2015.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed October 2015.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed October 2015.