

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

XIFAXAN 550MG ONLY
(rifaximin)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

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
AND
 - o The requested drug is being used as add-on therapy to lactulose

OR

- The patient has the diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
AND
 - o If the patient has previously received treatment with the requested drug, the patient is experiencing a recurrence of symptoms
AND
 - o 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, New Jersey: Salix Pharmaceuticals, Inc; October 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2022; Accessed March 14, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. <https://www.micromedexsolutions.com>. Accessed March 14, 2022.
4. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. *Hepatology*. 2014;60(2):715-735.
5. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021;116:17-44.