



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Xifaxan 550 mg Page: 1 of 3

Effective Date: 10/1/2023 Last Review Date: 8/17/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xifaxan 550 mg under the patient's prescription drug benefit.

Description:

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.

Compensial Uses

Small intestinal bacterial overgrowth (SIBO)³

Applicable Drug List:

Xifaxan 550mg

Policy/Guideline:

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

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

OR

- The requested drug is being prescribed for the treatment of irritable bowel syndrome with diarrhea (IBS-D)

AND



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- o The patient has NOT previously received treatment with the requested drug for irritable bowel syndrome with diarrhea (IBS-D)

OR

- o The patient has previously received treatment with the requested drug for irritable bowel syndrome with diarrhea (IBS-D)

AND

- 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 for the treatment of irritable bowel syndrome with diarrhea (IBS-D)

OR

- The requested drug is being prescribed for the treatment of small intestinal bacterial overgrowth (SIBO)

AND

- o The patient's diagnosis has been confirmed by ONE of the following: A) quantitative culture of upper gut aspirate, B) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test)

OR

- o The patient is experiencing a recurrence of small intestinal bacterial overgrowth (SIBO) after completion of a successful course of the requested drug

Approval Duration and Quantity Restrictions:

Approval:

- Hepatic Encephalopathy: 12 months
- Irritable Bowel Syndrome with Diarrhea and Small Intestinal Bacterial Overgrowth (SIBO): 14 days

References:

1. Xifaxan [package insert]. Bridgewater, New Jersey: Salix Pharmaceuticals, Inc; September 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed May 31, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/31/2023).
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.



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5. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021;116:17-44.
6. Pimentel M, Saad RJ, Long MD et al. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *Am J Gastroenterol* 2020;115:165-178.
7. Goshal UD, Sachdeva S, Goshal U et al. Asian-Pacific consensus on small intestinal bacterial overgrowth in gastrointestinal disorders: An initiative of the Indian Neurogastroenterology and Motility Association. *Indian Journal of Gastroenterology* (September-October 2022) 41(5);483-507.