

Effective Date: 12/2017
Revised: 7/2018, 10/2019
Reviewed: 12/2017, 7/2018, 10/2019, 8/2020, 5/2021, 6/2022, 5/2023, 6/2024
Scope: Medicaid

XIFAXAN (rifaximin)

POLICY

I. CRITERIA FOR INITIAL APPROVAL

A. Traveler's Diarrhea

Authorization of 1 month may be granted for treatment of traveler's diarrhea (TD) when all the following criteria are met:

1. TD caused by noninvasive strains of *Escherichia coli*
2. Member is 12 years of age or older
3. Member has experienced an inadequate treatment response, intolerance, or contraindication to both a fluoroquinolone (e.g., ciprofloxacin, levofloxacin) and azithromycin.

B. Irritable Bowel Syndrome with Diarrhea

Authorization of 1 month may be granted for treatment of irritable bowel syndrome with diarrhea in members 18 years of age or older when all the following criteria are met:

1. Member has experienced an inadequate treatment response, intolerance, or contraindication to two generic medications for diarrhea symptoms (e.g., loperamide and a bile acid sequestrant)
2. Member has abdominal pain/bloating and has experienced an inadequate treatment response, intolerance, or contraindication to short-term trials with two generic antispasmodic medications for abdominal pain such as dicyclomine, hyoscyamine immediate release or hyoscyamine extended release
3. Member has received less than a total of three 14-day course treatments.

C. Hepatic Encephalopathy

Authorization of 12 months may be granted for treatment of hepatic encephalopathy in members 18 years of age or older when the following criteria is met:

1. Member has experienced an inadequate treatment response, intolerance, or contraindication to lactulose for control of ammonia levels.

II. CONTINUATION OF THERAPY

A. Hepatic Encephalopathy

Authorization of 12 months may be granted for members 18 years of age or older who achieve or maintain positive clinical response with Xifaxan as evidenced by a decrease in serum ammonia levels and/or improvement in member's mental status.

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III. Approval Limits

- A. **Traveler's Diarrhea:** 200 mg tablet, 9 tablets
- B. **Irritable Bowel Syndrome with Diarrhea:** 550 mg tablet, 42 tablets
- C. **Hepatic Encephalopathy:** 550 mg tablet, 60 tablets

IV. REFERENCES

1. Xifaxan [package insert]. Bridgewater, New Jersey: Salix Pharmaceuticals, Inc; November 2023.
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.
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.