Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Xifaxan (rifaximin)**

Effective: February 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Xifaxan (rifaximin) 200 mg tablets are indicated for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in adults and pediatric patients 12 years of age and older.

Xifaxan (rifaximin) should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *E. coli*.

Xifaxan (rifaximin) 550 mg tablets are indicated for reduction in risk of overt hepatic encephalopathy recurrence in adults.

Xifaxan (rifaximin) 550 mg tablets are also indicated for the treatment of irritable bowel syndrome with diarrhea in adults.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xifaxan (rifaximin) for patients when **ALL** the following criteria are met:

For Treatment of Traveler's Diarrhea

1. The patient has a documented diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli*

For Hepatic Encephalopathy

1. The patient has a documented diagnosis of hepatic encephalopathy

AND

2. The patient has had trial and failure, inadequate response, intolerance, or contraindication to lactulose

For Irritable Bowel Syndrome with Diarrhea (IBS-D)

Initial authorization

1. The patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

Reauthorization

1. Documentation of a recurrence of IBS-D symptoms

AND

2. Documentation of a positive clinical response to therapy

For Small Intestine Bacterial Overgrowth (SIBO)

1. The patient has a documented diagnosis of small intestine bacterial overgrowth

AND

2. The prescribing physician is a gastroenterologist

AND

3. A. The patient has failed to respond to at least two different classes of antibiotic treatment (e.g., ciprofloxacin, metronidazole, amoxicillin-clavulanate, trimethoprim-sulfamethoxazole)

OR

B. The patient has contraindication to all these antibiotic treatments: ciprofloxacin, metronidazole, amoxicillin-clavulanate

Limitations

1. Xifaxan (rifaximin) would not be covered in the following instances:
    A. Treatment of diarrhea caused by pathogens other than E. coli
    B. Treatment of diarrhea complicated by fever or bloody stools
    C. Treatment of Irritable Bowel Syndrome with constipation
    D. Prevention of traveler's diarrhea
2. For traveler's diarrhea, coverage is limited to a 3-day course of therapy (9 tablets) of the 200 mg tablets in any 30-day period
3. For Hepatic Encephalopathy, coverage is limited to 60 tablets per 30 days of the 550 mg tablets.
4. For Irritable Bowel Syndrome with Diarrhea (IBS-D), coverage will be limited to 3 tablets of 550mg per day for one treatment cycle of 14 days. Xifaxan (rifaximin) for the treatment of IBS-D will only be authorized up to a maximum of three treatment cycles.
5. For Small Intestine Bacterial Overgrowth (SIBO), coverage is limited to 3 of the 550mg tablets per day for a 14 day treatment cycle. Coverage of Xifaxan for SIBO is limited to no more than two treatment cycles per 365 days. Subsequent treatment cycle requires reauthorization.
6. Duration of coverage for other non-FDA-approved indications that have been deemed medically necessary will be determined based on the dosing and length of treatment recommended by compendia for the requested indication. Subsequent approvals for non-FDA-approved indications will be reviewed on a case by case basis.

Codes

None

References

1. Lembo A, Pimentel M, Rao SS, et al., Repeat Treatment With Rifaximin Is Safe and Effective in Patients With Diarrhea-Predominant Irritable Bowel Syndrome. Gastroenterology. 2016;151(6):1113.
2. Loguercio C, Federico A, De Girolamo V, Ferrieri A, Del Vecchio Blanco C. Cyclic treatment of chronic hepatic encephalopathy with rifaximin. Results of a double-blind clinical study. Minerva Gastroenterol Dietol. 2003; 49(1):53-62.
3. Pimentel M et al. Rifaximin Therapy for Patients with Irritable Bowel Syndrome without Constipation. N Engl J Med 2011; 364: 22-32.
4. Ridola L, Zullo A, Hassan C, Saudi J. Rifaximin for treatment of hepatic encephalopathy: Some considerations. Gastroenterol. 2013; 19(1):56. doi: 10.4103/1319-3767.105930.
5. Sachdev A. H. and Pimentel M. Gastrointestinal bacterial overgrowth: pathogenesis and clinical significance. Ther Adv Chronic Dis. 2013 Sep; 4(5): 223–231. doi: 10.1177/2040622313496126
6. Xifaxan [package insert]. Raleigh, NC: Salix Pharmaceuticals, Inc.; June 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- February 14, 2023: Updated limitations to allow for coverage of Xifaxan for SIBO for no more than two treatment cycles per 365 days vs. 2 courses per life of plan.
- February 13, 2024: No changes
- February 11, 2025: No changes
- February 10, 2026: No changes
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.