

Commercial/Healthcare Exchange PA Criteria Effective: January 1, 2020

Prior Authorization: Xifaxan

Products Affected: Xifaxan 200 mg tablet, Xifaxan 550 mg tablet

Medication Description:

Xifaxan (rifaximin) is a semi-synthetic and non-systemic antibiotic derivative of rifampin. It blocks bacterial RNA synthesis by binding to the beta-subunit of DNA-dependent RNA polymerase. This results in inhibition of bacterial growth through prevention of bacterial protein synthesis.

Xifaxan (rifaximin) is approved for the treatment of Traveler's diarrhea caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older, the treatment of irritable bowel syndrome with diarrhea in adults, and to reduce the risk of over hepatic encephalopathy recurrence in adults.

Covered Uses:

1. Traveler's diarrhea, noninvasive strains of Escherichia coli
2. Hepatic encephalopathy; prophylaxis
3. Irritable bowel syndrome with diarrhea (IBS-D)

Exclusion Criteria:

1. Patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in Xifaxan.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions:

Traveler's diarrhea: 12 years of age or older

Hepatic encephalopathy and IBS-D: 18 years of age or older

Prescriber Restrictions: N/A

Coverage Duration:

Traveler's diarrhea: 10 days

Irritable Bowel Syndrome: 14 days

Hepatic encephalopathy: Initial – 6 months, Renewal – 12 months

Other Criteria:

Traveler's Diarrhea

Approve Xifaxan 200 mg tablets for 10 days if the patient meets the following criteria (A,B, C and D):

- A. Patient is 12 years of age or older; AND
- B. Patient has a confirmed diagnosis of traveler's diarrhea known to be caused by a noninvasive strain of Escherichia coli; AND
- C. Patient's disease is not complicated by fever or blood in the stool; AND

D. Patient has tried and failed, has a contraindication to, or has experienced significant adverse effects from, a fluoroquinolone antibiotic (e.g. ciprofloxacin).

Hepatic Encephalopathy, prophylaxis

Initial: Approve Xifaxan 550 mg tablets for 6 months if the patient meets the following criteria (A, B, and C):

- A. Patient is 18 years of age or older; AND
- B. Patient has a confirmed diagnosis of hepatic encephalopathy; AND
- C. Patient has tried and failed, has a contraindication to, or has experienced significant adverse effects from, nonabsorbable disaccharides (e.g., lactulose)

Renewal: Approve Xifaxan 550 mg tablets for 12 months if the patient meets the following criteria (A and B):

- A. Patient has achieved a reduction in fasting serum ammonia levels; AND
- B. Patient’s mental status changes have improved or resolved

Irritable Bowel Syndrome with diarrhea

Initial: Approve Xifaxan 550 mg tablets for 14 day if the patient meets the following criteria (A, B and C):

- A. Patient is 18 years of age or older; AND
- B. Patient has a confirmed diagnosis of irritable bowels syndrome with diarrhea; AND
- C. Patient has tried and failed, has a contraindication to, or has experienced significant adverse effects from, at least one of the following:
 - a. Antispasmodic (e.g. dicyclomine)
 - b. Anti-diarrheal (e.g. loperamide)

References:

1. Xifaxan [package insert]. Salix Pharmaceuticals, Inc. Bridgewater, NJ. January, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019