



Prior Authorization Approval Criteria

Xifaxan (rifaximin)

Generic name: rifaximin

Brand name: Xifaxan

Medication class: antibacterial

FDA-approved uses:

- Treatment of patients 12 years of age and older with travelers' diarrhea (TD) caused by noninvasive strains of E.coli
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients \geq 18 years of age

Available dosage forms: 200mg and 550mg tablets

Usual dose:

TD: 200mg three times a day for 3 days
HE: 550 mg twice a day (1100mg/day)
IBS: 550mg three times daily for 14 days

Approximate monthly cost: (based on AWP 2010)

TD: 81.45 for a 3 day treatment
HE: \$1,344.00/month
IBS: \$988 for 14-day course

Duration of therapy:

TD: 3 days
HE: varies
IBS: single 14-day course

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.

Traveler's Diarrhea:

- Prior authorization not required for 9 pills if treating traveler's diarrhea.

Hepatic encephalopathy:

- Must have clinically diagnosed condition of hepatic encephalopathy
- Treatment failure with nonabsorbable disaccharides (i.e. lactulose, lactitol).

Or

- Intolerant/Contraindication to treatment with formulary nonabsorbable disaccharide

Irritable Bowel Syndrome (IBS):

- If approved, only a single, 14-day course will be approved.
- Must have clinically documented moderate to severe IBS without constipation
- Must have moderate abdominal pain and bloating
- Must have tried psychological therapies*
- Must have failed dietary modification (including lactose restricted diet, if lactose-intolerant; exclusion of gas-producing foods; low carbohydrate diet and elimination of fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs).)
- Must have failed or was intolerant to antispasmodic agents*
- Must have failed or was intolerant to antidepressants (tricyclic antidepressants)

Criteria for continuation of therapy:

Travelers Diarrhea:

- Discontinue therapy if patient has persistent or worsening symptoms after 24-48 hours

Hepatic Encephalopathy:

- A decrease in fasting serum ammonia levels from baseline
- Improvements in patient's mental status

Caution:

- Pregnancy Category C, lactation unknown
- Teratogenic in animals, however, rifaximin is nonabsorbable and therefore unlikely to be Teratogenic to humans receiving oral preparations

Contraindication:

- Hypersensitivity to rifaximin (or other rifamycins such as rifampin) or any component of the formulation.

Not approved if:

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of rifaximin.
- E. coli is not suspected as the causative pathogen.
- Diarrhea is complicated by fever or bloody stool.
- Patient is being treated for dysentery.
- Diarrhea is associated with use of antibiotics.
- Hepatic encephalopathy patient has not attempted therapy with a formulary nonabsorbable disaccharide (as long as no contraindication exists).

Special considerations:

- Clinical trials data shows similar efficacy between rifaximin and lactulose for the treatment of hepatic encephalopathy
- Clinical trials data shows similar efficacy between rifaximin and ciprofloxacin for the treatment of travelers diarrhea
- *Notes:
 - Examples of psychological therapies include cognitive therapy, dynamic psychotherapy, hypnotherapy
 - Examples of antispasmodic agents include dicyclomine, hyoscyamine
- IBS: based on TARGET 1 and TARGET 2 trials; participants were at least 18 years old, patients with constipation-predominant IBS were excluded, as well as use of antibiotics within the previous 14 days or rifaximin use within the previous 60 days; all participants had moderate abdominal pain and bloating at baseline; short duration of follow-up (12 weeks); there is no data to support the long-term safety and efficacy of rifaximin for IBS symptoms.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/13/06
Rev. 09/08/10, 09/07/11