XIFAXAN

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
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<tbody>
<tr>
<td>Xifaxan</td>
<td>rifaximin</td>
<td>Per Medical Guidelines</td>
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**Approvable Criteria:**
- For the treatment of members (greater than or equal to 12 years of age) with travelers’ diarrhea caused by noninvasive strains of *Escherichia coli*.
- For reduction in risk of overt hepatic encephalopathy (HE) recurrence in members ≥ 18 years of age.
  - In the trials of rifaximin for hepatic encephalopathy, 91% of the patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed.
  - Rifaximin has not been studied in patients with model for end-stage liver disease (MELD) scores greater than 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.
- For the treatment of irritable bowel syndrome (IBS) with diarrhea.

**Approvable Duration:**
- For travelers’ diarrhea, the recommended dose is one 200mg tablet taken 3 times a day for 3 days. Approve one time for a quantity of 9.
- For hepatic encephalopathy, the recommended dose is one 550mg tablet taken twice daily. Approve for Calendar Year.
- For IBS with diarrhea, the recommended dose is one 550mg tablet taken three times a day for 14 days. Approve one time for a quantity of 42.
  - Patients experiencing a recurrence of symptoms may receive the same 14-day dosing regimen up to 2 additional times (maximum of 3 total treatment cycles per 365 days).
  - Additional treatment cycles will require authorization renewal.

**Exclusion Criteria:**
- Rifaximin tablets *will not* be approved in members with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*.
- Rifaximin tablets *will not* be approved in members for the off-label treatment of ulcerative colitis, Crohn’s disease, pouchitis, prophylaxis for GI surgery, diverticular disease, recurrent Clostridium difficile-associated diarrhea, or for any other treatment other than the FDA-approved diagnosis.

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*References:*