



## MEDICATION POLICY

**Generic Name:** Rifaximin

**Therapeutic Class or Brand Name:** Xifaxan®

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 11/24/17

**GPI Code:** 1600004900

### Prior Authorization Criteria (may be considered medically necessary when criterion I is met):

- I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
  - A. Traveler's Diarrhea caused by noninvasive strains of *Escherichia coli* (*E. coli*) and criteria 1 and 2 are met:
    1. Documented trial and failure of, or contraindication to, a fluoroquinolone (i.e. ciprofloxacin).
    2. Minimum age requirement: 12 years old.
  - B. Irritable Bowel Syndrome with diarrhea and criterion 1 is met:
    1. Minimum age requirement: 18 years old.
  - C. Hepatic Encephalopathy and criteria 1 and 2 are met:
    1. Documented trial and failure of, or contraindication to, lactulose.
    2. Minimum age requirement: 18 years old.

### Exclusion Criteria:

- Treatment of diarrhea caused by pathogens other than *Escherichia coli* (*E. coli*).
- Treatment of diarrhea complicated by fever or bloody stools.
- Prevention of Traveler's Diarrhea.

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- Traveler's Diarrhea:
  - Quantities of up to 9 of the 200mg tablets for one 3-day course of therapy per 30 days.

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- Irritable Bowel Syndrome with diarrhea:
  - Quantities of up to 42 of the 550mg tablets for one 14-day course of therapy per 90 days.
- Hepatic Encephalopathy:
  - Quantities of up to 60 of the 550mg tablets per 30 days.

### Approval Length:

- **Authorization:**
  - Traveler's Diarrhea: 1 time only per 30 days.
  - Irritable Bowel Syndrome with diarrhea: 1 time only per 90 days.
  - Hepatic Encephalopathy: 1 year.
- **Re-Authorization:**
  - Traveler's Diarrhea: N/A
  - Irritable Bowel Syndrome with diarrhea: patients who have a documented prior response to Xifaxan® but have relapsed may be authorized to receive up to a maximum of two additional courses of therapy (for a total of three courses of therapy).
  - Hepatic Encephalopathy: 1 year. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

### Appendix:

N/A

### References:

1. [http://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Xifaxan\\_rifaximin.pdf.ashx](http://www.fchp.org/providers/pharmacy/~media/Files/FCHP/Imported/Xifaxan_rifaximin.pdf.ashx).
2. <https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan>.
3. <https://securews.healthnowny.com/web/content/dam/COMMON/Drug%20Therapy%20Guidelines/X,Y,Z/Xifaxan.pdf>.
4. Medi-Span.
5. <https://shared.salix.com/shared/pi/xifaxan550-pi.pdf?id=812100>.
6. Facts & Comparisons® eAnswers.
7. [http://www.gastrojournal.org/article/S0016-5085\(14\)01089-0/pdf](http://www.gastrojournal.org/article/S0016-5085(14)01089-0/pdf).

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<b>Historical Tracking Of Changes Made To Policy</b>	
11/24/2017	<ol style="list-style-type: none"> <li><b>Updated</b> “<a href="https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct">https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct</a>” <b>to</b> “<a href="https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan">https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan</a>” <b>under References.</b></li> </ol>
8/29/2016	<ol style="list-style-type: none"> <li><b>Changed</b> “I. B. Irritable Bowel Syndrome, without constipation and criteria 1 and 2 are met: 1. Documented trial and failure of, or contraindication to, standard antibiotic treatment (i.e. ciprofloxacin, metronidazole); 2. Minimum age requirement: 18 years old” <b>to</b> “I. B. Irritable Bowel Syndrome with diarrhea and criterion 1 is met: 1. Minimum age requirement: 18 years old” <b>under Prior Authorization Criteria.</b></li> <li><b>Changed</b> “Irritable Bowel Syndrome, without constipation:...” <b>to</b> “Irritable Bowel Syndrome with diarrhea...” <b>under Quantity/Days Supply Restrictions.</b></li> <li><b>Changed</b> “Hepatic Encephalopathy: 6 months” <b>to</b> “Hepatic Encephalopathy: 1 year” <b>below Authorization under Approval Length.</b></li> <li><b>Changed</b> “Irritable Bowel Syndrome, without constipation...” <b>to</b> “Irritable Bowel Syndrome with diarrhea...” <b>below Authorization under Approval Length.</b></li> <li><b>Changed</b> “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective” <b>to</b> “Traveler's Diarrhea: N/A; Irritable Bowel Syndrome with diarrhea: patients who have a documented prior response to Xifaxan® but have relapsed may be authorized to receive up to a maximum of two additional courses of therapy (for a total of three courses of therapy); Hepatic Encephalopathy: 1 year. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective” <b>below Re-Authorization under Approval Length.</b></li> <li><b>Updated</b> “<a href="http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/xifaxan.pdf">http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/xifaxan.pdf</a>” <b>to</b> “<a href="https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct">https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct</a>” <b>under References.</b></li> <li><b>Added</b> “<a href="http://www.gastrojournal.org/article/S0016-5085(14)01089-0/pdf">http://www.gastrojournal.org/article/S0016-5085(14)01089-0/pdf</a>” <b>under References.</b></li> </ol>
4/21/2015	<ol style="list-style-type: none"> <li><b>Updated</b> “<a href="https://securews.healthnowny.com/wps/wcm/connect/fae718804345aaff9e97ff9f7ed9ec59/Xifaxan.pdf?MOD=AJPERES">https://securews.healthnowny.com/wps/wcm/connect/fae718804345aaff9e97ff9f7ed9ec59/Xifaxan.pdf?MOD=AJPERES</a>” <b>to</b> “<a href="https://securews.healthnowny.com/web/content/dam/COMMON/Drug%20Therapy%20Guidelines/X,Y,Z/Xifaxan.pdf">https://securews.healthnowny.com/web/content/dam/COMMON/Drug%20Therapy%20Guidelines/X,Y,Z/Xifaxan.pdf</a>” <b>and</b> “<a href="http://www.salix.com/assets/pdf/prescribe_info/xifaxanpi.pdf">http://www.salix.com/assets/pdf/prescribe_info/xifaxanpi.pdf</a>” <b>to</b> “<a href="https://shared.salix.com/shared/pi/xifaxan550-pi.pdf?id=812100">https://shared.salix.com/shared/pi/xifaxan550-pi.pdf?id=812100</a>” <b>under References.</b></li> <li><b>Added</b> “Facts &amp; Comparisons@ eAnswers” <b>under References.</b></li> </ol>
12/9/2013	<ol style="list-style-type: none"> <li><b>Adapted policy to new format.</b></li> <li><b>Added GPI Code.</b></li> <li><b>Changed</b> “Documented trial and failure of, or contraindication to, Ciprofloxacin” <b>to</b> “Documented trial and failure of, or contraindication to, a fluoroquinolone (i.e. ciprofloxacin)” <b>under Prior Authorization Criteria for Traveler’s Diarrhea diagnosis.</b></li> <li><b>Changed Quantity/Days Supply Restrictions from:</b>  “For Traveler’s Diarrhea treatment: one 3-day course of therapy (9 tablets) of the 200 mg tablets per 30 days; For Hepatic Encephalopathy treatment: 60 tablets per 30 days of the 550 mg tablets; For Irritable Bowel Syndrome, without constipation, treatment: one 14-day course of therapy (42 tablets) of the 550 mg tablets”  <b>to:</b>  “Traveler’s Diarrhea: Quantities of up to 9 of the 200mg tablets for one 3-day course of therapy per 30 days; Irritable Bowel Syndrome, without constipation: Quantities of up to 42 of the 550mg tablets for one 14-day course of therapy per 90 days; Hepatic Encephalopathy: Quantities of up to 60 of the 550mg tablets per 30 days”.</li> </ol>

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<i>Historical Tracking Of Changes Made To Policy</i>	
	<p>5. <b>Changed Authorization under Approval Length from:</b> “1 time only for Traveler's Diarrhea treatment; 1 time only for Irritable Bowel Syndrome, without constipation, treatment; 6 months for Hepatic Encephalopathy treatment” <b>to:</b> “Traveler's Diarrhea: 1 time only per 30 days; Irritable Bowel Syndrome, without constipation: 1 time only per 90 days; Hepatic Encephalopathy: 6 months”.</p> <p>6. <b>Changed Re-Authorization from</b> “An updated letter of medical necessity or progress notes showing improvement on medication” <b>to</b> “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective”.</p> <p>7. <b>Updated references</b> to include Medi-Span.</p>

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