



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: 8/29/16

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.
2. <https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct>.
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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Historical Tracking Of Changes Made To Policy	
8/29/2016	<ol style="list-style-type: none"> 1. Changed “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” to “I. B. Irritable Bowel Syndrome with diarrhea and criterion 1 is met: 1. Minimum age requirement: 18 years old” under Prior Authorization Criteria. 2. Changed “Irritable Bowel Syndrome, without constipation:...” to “Irritable Bowel Syndrome with diarrhea...” under Quantity/Days Supply Restrictions. 3. Changed “Hepatic Encephalopathy: 6 months” to “Hepatic Encephalopathy: 1 year” below Authorization under Approval Length. 4. Changed “Irritable Bowel Syndrome, without constipation...” to “Irritable Bowel Syndrome with diarrhea...” below Authorization under Approval Length. 5. Changed “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective” to “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” below Re-Authorization under Approval Length. 6. Updated “http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/xifaxan.pdf” to “https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/xifaxan-commercial-direct” under References. 7. Added “http://www.gastrojournal.org/article/S0016-5085(14)01089-0/pdf” under References.
4/21/2015	<ol style="list-style-type: none"> 1. Updated “https://securews.healthnowny.com/wps/wcm/connect/fae718804345aaff9e97ff9f7ed9ec59/Xifaxan.pdf?MOD=AJPERES” to “https://securews.healthnowny.com/web/content/dam/COMMON/Drug%20Therapy%20Guidelines/X,Y,Z/Xifaxan.pdf” and “http://www.salix.com/assets/pdf/prescribe_info/xifaxanpi.pdf” to “https://shared.salix.com/shared/pi/xifaxan550-pi.pdf?id=812100” under References. 2. Added “Facts & Comparisons® eAnswers” under References.
12/9/2013	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed “Documented trial and failure of, or contraindication to, Ciprofloxacin” to “Documented trial and failure of, or contraindication to, a fluoroquinolone (i.e. ciprofloxacin)” under Prior Authorization Criteria for Traveler’s Diarrhea diagnosis. 4. Changed Quantity/Days Supply Restrictions from: “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” to: “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”. 5. Changed Authorization under Approval Length from:

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<i>Historical Tracking Of Changes Made To Policy</i>	
	<p>“1 time only for Traveler's Diarrhea treatment; 1 time only for Irritable Bowel Syndrome, without constipation, treatment; 6 months for Hepatic Encephalopathy treatment”</p> <p>to:</p> <p>“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. Changed Re-Authorization from “An updated letter of medical necessity or progress notes showing improvement on medication” to “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. Updated references to include Medi-Span.</p>

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