

ALASKA MEDICAID  
Prior Authorization Criteria

**Xifaxan® (rifaximin)**

**Indications:**

“Xifaxan is a rifamycin antibacterial indicated for:

- Treatment of travelers’ diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.”<sup>1</sup>

**Dosage Form/Strength:**

Tablets: 200mg and 550mg

**Criteria for Approval:**<sup>1</sup>

*Xifaxan 200mg:*

- Patient is ≥ 12 years of age
- Diagnosis of traveler’s diarrhea caused by non-invasive strains of *E.coli*.
- For patients ≥ 18 years of age, has had a trial of a fluoroquinolone which is FDA indicated to treat TD; unless contraindicated by a patient allergy or a culture & sensitivity.

*Xifaxan 550mg:*

- Patient is ≥ 18 years of age; **AND,**
  - Diagnosis of either hepatic encephalopathy (HE); **AND,**
    - History of ineffective trial or subtherapeutic response to treatment with lactulose.
- OR**
- Diagnosis of Irritable bowel syndrome with diarrhea (IBS-D); **AND,**
    - Has not exceeded three 14 day courses of therapy per rolling 365 day period; **AND,**
    - Patient meets the Rome III Criterion for Irritable Bowel Syndrome diagnosis:<sup>2</sup>
      - Symptoms beginning at least 6 months prior to diagnosis; **AND,**
      - Symptoms have been experienced for the last 3 months; **AND,**
      - Patient experiences repetitive abdominal pain or discomfort, occurring at least 3 days monthly out of the previous 3 months.
      - Symptoms are associated with at least two of the following:
        - Defecating causes improvement of the symptoms
        - When the symptoms begin, the bowel movement frequency changes
        - When the symptoms begin, the stool appearance changes; **OR,**
    - Has already started a 14 day course of therapy as part of an inpatient hospital stay

**Criteria for Reauthorization Approval:**

- For a diagnosis of TD or HE:
  - Patient meets all of the criteria for the initial authorization; **AND,**
  - There is documented evidence of a positive clinical response to Xifaxan therapy.

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- For a diagnosis of IBS-D:
  - There is documented evidence of a positive clinical response to Xifaxan therapy as demonstrated by improvement in the patient's Rome III Criterion symptoms; **AND**,
  - The patient has experienced a recurrence of symptoms, and other causes of the symptom recurrence have been ruled out.

**Criteria for Denial:**

Any diagnosis other than IBS-D, hepatic encephalopathy, or traveler's diarrhea caused by non-invasive strains of *E.coli*.

*Xifaxan 200mg:*

- Patient is less 12 years of age; **OR**,
- No trial of a fluoroquinolone for patients greater than or equal to 18 years of age, unless contraindicated by allergy or a culture and sensitivity.

*Xifaxan 550mg:*

- Patient is less than 18 years of age; **OR**,
  - For a diagnosis of HE: No history of an ineffective trial or subtherapeutic response to lactulose.
  - For a diagnosis of IBS-D: Has previously completed three 14 day courses of therapy per rolling 365 day period.

**Length of Authorization – Initial coverage:**

*Xifaxan 200mg:*

- Prior authorization may be approved for one 3-day course of therapy.

*Xifaxan 550mg:*

- Prior authorization for a diagnosis of HE may be approved for 1 year.
- Prior authorization for a diagnosis of IBS-D may be approved for 14 days.

**Length of Authorization – Reauthorization:**

*Xifaxan 200mg:*

- TD: Reauthorization will be allowed three times (total of 4 courses of Xifaxan therapy allowed), upon additional travel occurring per rolling 365 days.

*Xifaxan 550mg:*

- HE: Reauthorization may be approved for 1 year.
- IBS-D: Reauthorization may be considered starting 10 weeks after the end of the last course of Xifaxan. Approval for an additional 14 days, up to a maximum of 3 treatment courses (14 days each) per rolling 365 days.

**Quantity Limit:**

*Xifaxan 200mg:*

- TD: The dispensing limit is 3 tablets per day, up to a maximum of 3 days.

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*Xifaxan 550mg:*

- HE: The dispensing limit is 2 tablets per day.
- IBS-D: The dispensing limit is 3 tablets per day, up to a maximum of 14 days.

**Mechanism of Action:**

“Rifaximin is a semi-synthetic derivative of rifampin and acts by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase blocking one of the steps in transcription. This results in inhibition of bacterial protein synthesis and consequently inhibits the growth of bacteria.”<sup>1</sup>

**References / Footnotes:**

<sup>1</sup> Xifaxin® package insert: Salix Pharmaceuticals. Bridgewater, NJ. November 2015.  
<http://www.xifaxan550.com/assets/pdfs/xifaxan550-pi.pdf> Accessed 1/11/2016.

<sup>2</sup> Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders. Appendix A: Rome III Diagnostic Criteria for FGIDs. Functional Bowel Disorders. Page 889.  
[http://www.romecriteria.org/assets/pdf/19\\_RomeIII\\_apA\\_885-898.pdf](http://www.romecriteria.org/assets/pdf/19_RomeIII_apA_885-898.pdf). Accessed 1/11/2016.

<sup>3</sup> National Collaborating Centre for Nursing and Supportive Care. “Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care.” London (UK): National Institute for Health and Care Excellence (NICE). February, 2008.  
[http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0009973/pdf/PubMedHealth\\_PMH0009973.pdf](http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0009973/pdf/PubMedHealth_PMH0009973.pdf)  
Accessed 11/4/2015.

<sup>4</sup> Chang AL, Lembo SS. “American Gastroenterological Association Institute Technical Review on the Pharmacological Management of Irritable Bowel Syndrome.” November 2014 Volume 147, Issue 5, Pages 1149–1172.e2 [http://www.gastrojournal.org/article/S0016-5085\(14\)01090-7/fulltext](http://www.gastrojournal.org/article/S0016-5085(14)01090-7/fulltext)

<sup>5</sup> Triantafyllou K, Sioulas AD, Giamarellos-Bourboulis EJ. “Rifaximin: The Revolutionary Antibiotic Approach for Irritable Bowel Syndrome.” *Mini Rev Med Chem*. 2015 Jul 21. [Epub ahead of print]

<sup>6</sup> Saadi M, McCallum RW. “Rifaximin in irritable bowel syndrome: rationale, evidence and clinical use.” *Ther Adv Chronic Dis*. 2013 Mar; 4(2): 71–75.

<sup>7</sup> Wilkins T, Pepitone C, Alex B, Schade RR. “Diagnosis and Management of IBS in Adults.” *Am Fam Physician*. 2012 Sep 1;86(5):419-426. <http://www.aafp.org/afp/2012/0901/p419.html>

<sup>8</sup> Connor B. “Travelers’ Health. The Pre-Travel Consultation: Travelers’ Diarrhea.” Centers for Disease Control and Prevention. Atlanta, GA. July 10, 2015. Accessed 1/12/2016.

<sup>9</sup> Ferenci P. “Hepatic encephalopathy in adults: Treatment.” Up to Date. January 6, 2016.  
<http://www.uptodate.com/contents/hepatic-encephalopathy-in-adults-treatment> . Accessed 1/12/2016.

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