

Policy Name:	Xifaxan (rifaximin)	Policy#:	1613P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Xifaxan (rifaximin)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Xifaxan (rifaximin) if the following criteria are met.

Criteria

1. Coverage Criteria for Xifaxan 200mg

- 1.1 Member is age 12 years or older
- 1.2 Documented diagnosis of travelers' diarrhea caused by non-invasive strains of *Escherichia coli*
- 1.3 Documented failure to respond or contraindication to one of the following medications
 - A fluoroquinolone
 - Azithromycin
- 1.4 Managed Dose Limit (MDL) of 9 tablets per 30 days per rolling 12 months
- 1.5 Approval Period: 9 tablets per 30 days within 12 months

2. Coverage Criteria for Xifaxan 550mg for Hepatic Encephalopathy

- 2.1 Member is age 18 years or older
- 2.2 Documented diagnosis of Hepatic Encephalopathy
- 2.3 Documented failure to respond or contraindication to lactulose
- 2.4 Managed Dose Limit (MDL) of 60 tablets per 30 days
- 2.5 Approval Period: 12 months

3. Coverage Criteria for Xifaxan 550mg for IBS-D without Constipation

- 3.1 Member is age 18 years or older
- 3.2 Documented diagnosis of moderate to severe Irritable Bowel Syndrome with Diarrhea, defined as the presence of loose or watery stools with 25% of bowel movements and hard or lumpy stools with < 25% of bowel movements
- 3.3 Documented failure to respond or contraindication to any THREE of the following:
 - loperamide
 - bile acid sequestrant (cholestyramine, colestipol, colesevelam)
 - antispasmodic agent (dicyclomine, hyoscyamine)
 - tricyclic antidepressant (amitriptyline, nortriptyline, and imipramine)
- 3.4 Managed Dose Limit (MDL) of 42 tablets per 14 days
- 3.5 Approval Period: 42 tablets per 14 days within 12 months; each individual treatment will require a new authorization
 - Maximum of 3 treatments per year

4. Coverage Criteria for Xifaxan for Small Intestine Bacterial Overgrowth

- 4.1 Documented diagnosis of Small Intestine Bacterial Overgrowth measured by hydrogen breath test or duodenal aspirate and culture

- 4.2 Ordered by a Gastroenterologist (stomach doctor)
- 4.3 Documented failure to respond to at least one previous antibiotic
- 4.4 Managed Dose Limit (MDL) of 42 tablets per 14 days
- 4.5 Approval Period: 42 tablets per 14 days within 12 months; each individual treatment will require a new authorization
 - Maximum of 3 treatments per year

CPT Codes

HCPCS Codes

References

1. Xifaxan (rifaximin) [Package Insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc; Revised October 2023.
2. Pimentel M, Saad RJ, Long MD, Rao SSC. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. Am J Gastroenterol 2020; 115:165.
3. Lembo A, Sultan S, Chang L, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology. 2022 Jul;163(1):137-151.
4. Lembo A, Pimentel M, Rao SS, et al. Repeat treatment with rifaximin is safe and effective in patients with diarrhea-predominant irritable bowel syndrome. Gastroenterology. 2016;151(6):1113-1121.
5. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. Hepatology. 2014;60(2):715-735.

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DISCLAIMER

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