

Pharmacy Policy Bulletin

Title: Rifaximin (Xifaxan®)

Policy #: Rx.01.182

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for **rifaximin (Xifaxan®)** as provided under the member's prescription drug benefit.

▸ Description:

Irritable bowel syndrome (IBS), a common, functional gastrointestinal disorder, is defined as abdominal discomfort associated with altered bowel habits. Three subtypes of IBS exist: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), and mixed type (IBS-M). Diagnosis of IBS is based solely on clinical criteria as there are no radiologic or endoscopic abnormalities in IBS and no biomarker has proven reliable for diagnosis. Approximately 10-15% of the general adult population is affected by IBS.

Hepatic encephalopathy (HE) is defined as brain dysfunction caused by liver insufficiency and/or portosystemic shunting. It manifests as a wide spectrum of neurological or psychiatric abnormalities ranging from subclinical alterations to coma.

Rifaximin (Xifaxan®), a semisynthetic antibiotic, is derived from rifampin. It inhibits bacterial protein synthesis and growth by binding to the beta-subunit of bacterial DNA-dependent RNA polymerase, blocking one of the steps in transcription. Rifaximin 550mg is indicated for reduction in risk of overt HE recurrence in adults and for treatment of IBS-D in adults. When treating IBS-D, the course of therapy is 14 days. The regimen may be repeated up to 2 times.

▸ Policy:

Rifaximin (Xifaxan®) 550 mg is approved when ONE of the following are met:

- A. Diagnosis of hepatic disease with risk for hepatic encephalopathy (ie previous episode of hepatic encephalopathy, advanced liver disease, hepatocellular carcinoma) AND inadequate response or inability to tolerate lactulose; or
- B. Diagnosis of irritable bowels syndrome- diarrhea AND inadequate response or inability to tolerate BOTH of the following:
 - 1. Tricyclic antidepressant or selective serotonin reuptake inhibitor; and
 - 2. Antispasmodic

Duration of approval:

- A. Hepatic disease with risk for encephalopathy: indefinite (Maximum daily dose 2/day)
- B. Irritable bowel syndrome- diarrhea: max of 14 days/84 days (Maximum daily dose 3/day)

Reauthorization criteria

Rifaximin (Xifaxan®) is reapproved when all of the following are met:

- A. Diagnosis of irritable bowel syndrome – diarrhea; and
- B. Member does not exceed 3 courses (42 days) of therapy; and
- C. No documentation of rifaximin (Xifaxin®) treatment within the last 10 weeks.

▸ Black Box Warning:

None

▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ References:

American Association for the Study of Liver Diseases and European Association for the Study of the Liver. Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by the European Association for the Study of the Liver and the American Association for the Study of Liver Diseases.


Journal of Hepatology. Available from: <http://www.easl.eu/medias/cpg/Hepatic-Encephalopathy-Chronic-Liver-Disease/English-report.pdf>. Accessed July 24, 2018.

Ford AC, Moayyedi P, Lacy, BE, et al. American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol. 2014; 109:S2-S26; doi: 1001038/ajg.2014.187

Weinberg DS, Smalley W, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1146-48.

Xifaxan® (rifaximin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; November 2016. Accessed July 24, 2018.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Xifaxan®	Rifaximin

Cross References:

N/A

Policy Version Number:	7.00
P&T Approval Date:	July 12, 2018
Policy Effective Date:	October 01, 2018
Next Required Review Date:	July 12, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.