

Xifaxan (rifaximin) 550 mg Tablets

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Xifaxan (rifaximin) 550 mg Tablets	1
Summary	1
Definitions	2
Clinical Indications	2
Medical Necessity Criteria for Initial Clinical Review	2
Initial Indication-Specific Criteria	2
Hepatic Encephalopathy, Treatment or Prevention:	2
For the treatment of Irritable Bowel Syndrome with diarrhea:	3
For the treatment of Small Intestinal Bacterial Overgrowth (SIBO):	3
Medical Necessity Criteria for Subsequent Clinical Review	4
Subsequent Indication-Specific Criteria	4
Hepatic Encephalopathy, Treatment or Prevention	4
For the treatment of Irritable Bowel Syndrome with diarrhea:	4
For the treatment of Small Intestinal Bacterial Overgrowth (SIBO):	4
Experimental or Investigational / Not Medically Necessary	5
References	5
Clinical Guideline Revision / History Information	7

Summary

Xifaxan (rifaximin) is an antibiotic that primarily targets the gastrointestinal tract, available in two formulation strengths - 200 mg tablets and 550 mg tablets. It inhibits bacterial and mycobacterial RNA synthesis, thereby disrupting protein production in these microorganisms. Rifaximin is FDA indicated for use in hepatic encephalopathy, irritable bowel syndrome with diarrhea, and traveler's diarrhea, as well as for off-label use in small intestinal bacterial overgrowth (SIBO). Given its minimal absorption in the gastrointestinal tract, its effects remain largely localized. The 200 mg formulation is used for treatment of traveler's diarrhea while the 550 mg formulation is intended for the treatment of hepatic encephalopathy, irritable bowel syndrome with diarrhea, and SIBO. The 550 mg dosage form is also used for the off-label use of acute, refractory pouchitis. The most common adverse reactions associated with rifaximin include abdominal pain and nausea.

This policy covers only the 550 mg tablet dosage form on Xifaxan (rifaximin).

Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Hepatic encephalopathy" is a decline in brain function that occurs as a result of severe liver disease. This is often due to an accumulation of toxins, such as ammonia, which are not effectively cleared by a damaged liver.

"Irritable bowel syndrome" is a chronic functional disorder of the gastrointestinal tract characterized by a combination of symptoms including chronic abdominal pain, bloating, and changes in bowel habits in the absence of any visible damage or disease.

"Small Intestinal Bacterial Overgrowth (SIBO)" is a condition characterized by an abnormal increase in the overall bacterial population in the small intestine, particularly types of bacteria not typically found in that part of the digestive tract.

"Traveler's diarrhea" is an intestinal infection that commonly causes loose stools and abdominal cramps. It's usually acquired during travel to areas with poor sanitary conditions affecting food and water.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Hepatic Encephalopathy, Treatment or Prevention:

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL the following criteria are met:

1. The member is age 18 years or older; *AND*
2. The member has a diagnosis of hepatic encephalopathy; *AND*
3. Xifaxan (rifaximin) 550mg is being prescribed for ONE (1) of the following:
 - a. to be added to lactulose therapy; *or*
 - b. the member is unable to use, or has tried and failed lactulose (i.e., the member has intolerable side effects, ineffectiveness after a specified duration, or specific worsening symptoms with lactulose)^[s].

If the above prior authorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 6 months.^[s]

For the treatment of Irritable Bowel Syndrome with diarrhea:

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL the following criteria are met:

1. The member is age 18 years or older; *AND*
2. The member has a diagnosis of irritable bowel syndrome with diarrhea.

If the above prior authorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 14 days.^[s]

For the treatment of Small Intestinal Bacterial Overgrowth (SIBO):

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL the following criteria are met:

1. The member has a diagnosis of small intestinal bacterial overgrowth, confirmed through a breath test or other appropriate diagnostic methods; *AND*
2. The member is unable to use, or has tried and failed ONE (1) of the following^[s]:
 - a. Amoxicillin/Clavulanic Acid; *or*
 - b. Ciprofloxacin; *or*
 - c. Doxycycline; *or*
 - d. Metronidazole; *or*
 - e. Neomycin; *or*
 - f. Sulfamethoxazole/Trimethoprim; *or*
 - g. Tetracycline

If the above prior authorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 14 days.^[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Medical Necessity Criteria

Hepatic Encephalopathy, Treatment or Prevention

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL of the following criteria are met:

1. The member meets the above [Initial Indication-Specific Criteria - Hepatic Encephalopathy, Treatment or Prevention](#); *AND*
2. There is documentation showing positive clinical benefit, improvement (such as reduction in the severity/frequency of hepatic encephalopathy episodes), or stabilization of hepatic encephalopathy symptoms with Xifaxan (rifaximin) therapy.

If the above reauthorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for up to 6-months.^[s]

For the treatment of Irritable Bowel Syndrome with diarrhea:

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL of the following criteria are met:

1. The member is age 18 years or older; *AND*
2. The member has a diagnosis of irritable bowel syndrome with diarrhea; *AND*
3. The member is experiencing a recurrence of symptoms; *AND*
4. The member has not received more than 3 total treatment cycles of 14 days each in the last 365 days.

If the above reauthorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for up to 14 days at a time (up to 3 total treatment cycles per year).^[s]

For the treatment of Small Intestinal Bacterial Overgrowth (SIBO):

The Plan considers Xifaxan (rifaximin) 550mg medically necessary when ALL of the following criteria are met:

1. The member has a diagnosis of small intestinal bacterial overgrowth; *AND*
2. The member is experiencing a recurrence of symptoms; *AND*
3. The member has not received more than 2 total treatment cycles of 14 days each in the last 90 days.

If the above reauthorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 14 days at a time (up to 2 total treatment cycles).^[s]

Experimental or Investigational / Not Medically Necessary^[s]

Xifaxan (rifaximin) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

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