

## Xifaxan (rifaximin)

### 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.*

### 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 most common adverse reactions associated with rifaximin include abdominal pain and nausea.

### Definitions

**"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.

#### **Medical Necessity Criteria for Authorization**

The Plan considers **Xifaxan (rifaximin)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

#### **For Hepatic Encephalopathy, treatment or prevention:**

#### **Medical Necessity Criteria for Initial Authorization**

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 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).

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

#### **Medical Necessity Criteria for Reauthorization**

Reauthorization for 6 months will be granted when all criteria for initial authorization are met and there is documentation showing positive clinical benefit or improvement (such as reduction in the severity/frequency of hepatic encephalopathy episodes) with Xifaxan therapy.

**For the treatment of Irritable Bowel Syndrome with diarrhea:**

**Medical Necessity Criteria for Initial Authorization**

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; **AND**
3. The member is unable to use, or has tried and failed **TWO** of the following:
  - a. Antispasmodic agents (such as dicyclomine, hyoscyamine); **or**
  - b. Antidiarrheal agents (such as loperamide); **or**
  - c. Tricyclic antidepressants (such as amitriptyline, nortriptyline, imipramine)

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

**Medical Necessity Criteria for Reauthorization**

Reauthorization will be granted 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 prior authorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 14 days at a time (up to 3 total treatment cycles per year).**

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

**Medical Necessity Criteria for Initial Authorization**

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 small intestinal bacterial overgrowth, confirmed through a breath test or other appropriate diagnostic methods; **AND**
3. The member is unable to use, or has tried and failed **ONE** of the following:
  - 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.**

### Medical Necessity Criteria for Reauthorization

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

**If the above prior authorization criteria are met, Xifaxan (rifaximin) 550mg will be approved for 14 days at a time (up to 2 total treatment cycles).**

### Experimental or Investigational / Not Medically Necessary

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

### References

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#### Clinical Guideline Revision / History Information

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