Oscar Clinical Guideline: Xifaxan (rifaximin) 550 mg Tablets (PG022, Ver. 8)

Xifaxan (rifaximin) 550 mg Tablets

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

"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.

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).

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

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*; AND*
3. The member is unable to use, or has tried and failed TWO (2) 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.

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:
    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.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Hepatic encephalopathy, Treatment or Prevention
Reauthorization for up to 6 months will be granted when all applicable criteria for initial authorization are met and 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.

For the treatment of Irritable Bowel Syndrome with diarrhea:
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 up to 14 days at a time (up to 3 total treatment cycles per year).

For the treatment of Small Intestinal Bacterial Overgrowth (SIBO):
Reauthorization will be granted 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 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.

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