Rifaximin in Irritable Bowel Syndrome With Diarrhea (IBS-D) Criteria for Use

August 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for rifaximin.

- ☐ Known hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any other component of rifaximin.
- ☐ No documented benefit from prior rifaximin therapy for irritable bowel syndrome with diarrhea (IBS-D).

Inclusion Criteria

ALL the following must be selected to meet criteria:

- ☐ Patient is under the care of a VA or VA Community Care gastroenterologist or locally designated provider qualified to diagnose and treat both symptomatic small intestinal bacterial overgrowth (SIBO) and IBS-D.
- ☐ Moderate to severe IBS-D (with or without SIBO).
- ☐ Moderate to severe symptoms (e.g., pain, bloating) continue or recur despite treatment.
- ☐ Trial of **soluble fiber** (e.g., psyllium) for 4 weeks unless it is medically inadvisable or was not tolerated.
- ☐ Trial of a **tricyclic antidepressant** (e.g., desipramine, nortriptyline) for 4 weeks unless it is medically inadvisable (e.g., elderly, suicidal ideation, QT prolongation, etc.) or was not tolerated.

Additional Inclusion Criteria

If applicable, the following must be selected to meet criteria.

- ☐ If **female with severe, chronic IBS-D (generally ≥ 6 months)**: Trial of **alosetron** for 4 weeks unless medically inadvisable or was not tolerated.

Other Justification

- ☐ _____

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for rifaximin in IBS-D.

Section	Issues for Consideration
Use of Rifaximin for SIBO and IBS-D	• Some patients with SIBO may have IBS, and vice versa. • **Rifaximin is not FDA-approved for the treatment of SIBO.** • Rifaximin is FDA-approved for the treatment of IBS-D in adults. ○ Rifaximin for IBS should be restricted to patients who have the IBS-D subtype and have not responded to effective and less costly symptom-based alternative therapies.
Dosage and Administration	• The approved dose for IBS-D is 550 mg 3 times a day for 14 days.
Dispensing Limit	• Authorize one course of rifaximin with a maximum dispensing limit of three 200-mg or 550-mg tablets per day for up to 14 days.
Alosetron REMS Program	• See Alosetron Risk Evaluation and Mitigation Strategy (REMS) at https://www.alosetronrems.com/ • The purpose of the Alosetron REMS program is to reduce the risk of serious gastrointestinal adverse reactions including ischemic colitis and serious complications of constipation.

Revisions:

August 2024. Removed limit of 3 treatment courses. Composite CFU changed to separate CFU by indication.
November 2021 (For SIBO, added two Exclusion Criteria previously noted under old Renewal Criteria; removed statements referring to renewals and refills, removed requirement for re-evaluation of patients prior to renewals or refills; retitled Inclusion Criteria for SIBO to "Treatment" of SIBO; changed previous ciprofloxacin from a note to an Inclusion Criterion for rifaximin treatment; added new Inclusion Criteria for rifaximin prophylaxis previously noted under old Renewal Criteria. For IBS-D, updated prior drugs to be consistent with the 2021 American College of Gastroenterology guideline on management of IBS by removing bile acid sequestrants, antispasmodics, antidiarrheals / loperamide, and low FODMAP diet, and adding soluble fiber and alosetron. Reformatted criteria for Cerner.)

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