Rifaximin in Treatment of Symptomatic Small Intestinal Bacterial Overgrowth 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 small intestinal bacterial overgrowth (SIBO).
- ☐ Reoccurrences of SIBO after durable response (e.g., ≥ 3 months) to one of the antibiotic regimens listed under **Additional Inclusion Criteria**. These reoccurrences should be retreated rather than proceed to rifaximin.[1]

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 symptomatic SIBO
- ☐ Documented diagnosis or working diagnosis of **SIBO without irritable bowel syndrome with diarrhea (IBS-D)** based on typical clinical presentation and, if testing is feasible, positive carbohydrate breath test or jejunal aspirate culture

Additional Inclusion Criteria

Symptoms that do not respond to a 7- to 10-day therapeutic trial of ONE of the following, unless the treatment is medically inadvisable, or the patient has a history of intolerance to the treatment:

- ☐ **Metronidazole** alone (250–500 mg 2–3 times a day; maximum two courses in a 6-month period)
- ☐ **Metronidazole in combination** with either **cephalexin** (500 mg 3–4 times a day) or **sulfamethoxazole / trimethoprim** double-strength (1 tab 2 times a day)
- ☐ **Amoxicillin-clavulanate** 500 mg 3 times a day or 875 mg 2 times a day
- ☐ **Neomycin** 500 mg 2 times a day
- ☐ **Previous ciprofloxacin** (250–500 mg twice a day) for SIBO. May count as the required prior antibiotic if already tried. It is not recommended because of its adverse effect profile.[1]

Other Justification

- ☐ _____

Footnotes

[1] Ciprofloxacin-naïve patients with SIBO should first be tried on one of the other antibiotics listed under **Additional Inclusion Criteria**.

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for rifaximin in SIBO.

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.
Dosage and Administration	• **For SIBO without IBS-D**: 200 mg 3 times a day for 7 days to 550 mg 3 times a day for 10 days. o Clinical study doses for SIBO have ranged from 200 to 550 mg 3 times a day, and duration has often been 7 to 10 days (range, 5 to 28 days). o The optimal dosage regimen of rifaximin in SIBO has not been determined
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.
Retreatment for SIBO	• Additional retreatments (renewals or refills) do not require re-evaluation of the patient if an initial course of rifaximin had been previously approved.
Prophylaxis for Recurrent SIBO	• If the patient benefited from metronidazole or other prior antibiotic therapy, has 4 or more distinct and well-documented SIBO episodes in one year, and has risk factors for recurrent SIBO, then that antibiotic may be used for prophylaxis. See **Rifaximin in Prophylaxis of Recurrent SIBO Criteria**.

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.)

Original: November 2017

Contact: Francine Goodman, PharmD, BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)