PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

XIFAXAN 550 MG ONLY
(rifaximin)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Hepatic Encephalopathy

Xifaxan is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.
In the placebo-controlled trial of Xifaxan for HE, 91% of the patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed.
Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) scores >25, and only 8.6% of patients in the placebo-controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction.

Irritable Bowel Syndrome with Diarrhea

Xifaxan is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Compendial Uses

Small intestinal bacterial overgrowth (SIBO)[3]

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed to reduce the risk of overt hepatic encephalopathy (HE) recurrence
  AND
  - The requested drug is being used as add-on therapy to lactulose

OR

- The requested drug is being prescribed for the treatment of irritable bowel syndrome with diarrhea (IBS-D)
  AND
  - The patient has NOT previously received treatment with the requested drug for irritable bowel syndrome with diarrhea (IBS-D)

  OR
  - The patient has previously received treatment with the requested drug for irritable bowel syndrome with diarrhea (IBS-D)

    AND
    - The patient is experiencing a recurrence of symptoms

    AND
    - The patient has received fewer than three 14-day courses of treatment with the requested drug for the treatment of irritable bowel syndrome with diarrhea (IBS-D)

OR

- The requested drug is being prescribed for the treatment of small intestinal bacterial overgrowth (SIBO)
  AND

- The patient's diagnosis has been confirmed by ONE of the following: A) quantitative culture of upper gut aspirate, B) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test)

OR

- The patient is experiencing a recurrence of small intestinal bacterial overgrowth (SIBO) after completion of a successful course of the requested drug

Duration of Approval (DOA):

- 681-A:
  - Hepatic Encephalopathy (HE): DOA: 12 months
  - Irritable Bowel Syndrome with Diarrhea (IBS-D): DOA: 14 days
  - Small Intestinal Bacterial Overgrowth (SIBO): DOA: 14 days

REFERENCES

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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *02/28/2024*).
4. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. *Hepatology*. 2014;60(2):715-735.
5. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021;116:17-44.
6. Pimentel M, Saad RJ, Long MD, et al. ACG Clinical Guideline: Small Intestinal Bacterial Overgrowth. *Am J Gastroenterol.* 2020;115:165-178.
7. Goshal UD, Sachdeva S, Goshal U et al. Asian-Pacific consensus on small intestinal bacterial overgrowth in gastrointestinal disorders: An initiative of the Indian Neurogastroenterology and Motility Association. *Indian J Gastroenterol.* 2022;41(5):483-507.