AdvancedHealth
Bridging the Future of Healthcare

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Rifaximin (Xifaxan®) Drug Use Criteria

Created: 4/2026
Reviewed: 4/2026

GUIDELINE FOR USE:

Initial Request:

1. Does the member have an OHP-funded condition?

    a. If yes, go to 2
    b. If no and member does not meet criteria for EPSDT/YSHCN, deny as not meeting criteria.

2. Is the prescribed medication and dose supported by FDA-approved indications and dosing?

    a. If yes, go to 3
    b. b. If no, deny as not meeting criteria

3. Is the request for hepatic encephalopathy associated with chronic liver disease?

    a. If yes, go to 4
    b. If no, go to 7

4. Has the member experienced at least one prior episode of overt hepatic encephalopathy?

    a. If yes, go to 5
    b. If no, deny as not meeting criteria

5. Has the member had an adequate trial (of lactulose at maximally tolerated dose OR documented intolerance/contraindication?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria

6. Will rifaximin be used in combination with lactulose (unless contraindicated)?

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a. If yes, approve for maintenance therapy
b. If no, deny as not meeting criteria

7. Is the request for Irritable Bowel Syndrome with Diarrhea (IBS-D) in a member less than 21 years of age (EPSDT) or for a member qualifying for YSHCN status?

   a. If yes, go to 8
   b. If no, deny as not meeting criteria (non-funded condition)

8. Has the member failed conventional therapy (e.g., loperamide, antispasmodics, dietary modification)?

   a. If yes, go to 9
   b. If no, deny as not meeting criteria

9. Is documentation provided supporting moderate to severe symptoms?

   a. If yes, approve for up to 14-day course
   b. If no, deny as not meeting criteria

Renewal Criteria:

1. Is the request for hepatic encephalopathy prevention?

   a. If yes, go to 2
   b. If no, deny as not meeting criteria

2. Does a review of medication fill history support consistent use since the last renewal, with good compliance?

   a. If yes, go to 3
   b. If no, deny as not meeting criteria

3. Has the member demonstrated clinical benefit (e.g., reduced HE recurrence or hospitalizations)?
   a. If yes, approve for up to 12 months
   b. If no, deny as not meeting criteria

4. Is there documentation demonstrating continued clinical benefit from the nebulized medication (e.g., symptom improvement, reduced exacerbations, improved pulmonary status)?

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a. If yes, go to 3.
b. If no, deny as not meeting criteria.

5. Is the requested dose and quantity within FDA labeling and consistent with clinical guidelines?
   a. If yes, approve for up to 12 months.
   b. If no, deny as not meeting criteria.

Rationale: To ensure appropriate use of rifaximin consistent with clinical guidelines, requiring first-line lactulose therapy and limiting use to OHP-funded conditions.

References:

1. American Association for the Study of Liver Diseases; European Association for the Study of the Liver. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline. *Hepatology.* 2014;60(2):715-735.
2. Bass NM, Mullen KD, Sanyal A, et al. Rifaximin treatment in hepatic encephalopathy. *N Engl J Med.* 2010;362(12):1071-1081.
3. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline by AASLD and EASL. *J Hepatol.* 2014;61(3):642-659.
4. Oregon Health Authority. Health Evidence Review Commission: Prioritized List of Health Services. Updated periodically.
5. Oregon Health Authority. General Rules and Guidance for Pharmacy Prior Authorization.