Clinical Policy Title:	rifaximin
Policy Number:	RxA.314
Drug(s) Applied:	Xifaxan®
Original Policy Date:	02/07/2020
Last Review Date:	4/27/26
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hepatic Encephalopathy (must meet all):

1. Diagnosis of HE and prescribed for reducing risk of overt HE recurrence;
2. Member meets (a or b):
   a. Xifaxan® is prescribed as add-on to lactulose therapy, unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of lactulose monotherapy in the past 30 days, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months, Split-fill

B. Irritable Bowel Syndrome with Diarrhea (must meet all):

1. Diagnosis of IBS-D;
2. Trial and failure of BOTH of the following (a AND b), unless contraindicated or clinically significant adverse effects are experienced:
   a. Anti-diarrheal agent (e.g., loperamide);
   b. Antispasmodic (e.g., dicyclomine, hyoscyamine);

Approval Duration
All Lines of Business (except Medicare): 14 days

C. Travelers' Diarrhea (must meet all):

1. Diagnosis of TD;
2. Trial and failure of azithromycin 1000 mg as a single dose, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 3 days

D. Small Intestinal Bacterial Overgrowth (off-label) (must meet all):

1. Diagnosis of small intestinal bacterial overgrowth (SIBO);

Approval Duration
All Lines of Business (except Medicare): 14 days

II. Continued Therapy Approval

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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A. Hepatic Encephalopathy (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Xifaxan® is being used concurrently with lactulose, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Irritable Bowel Syndrome with Diarrhea (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Member has not had ≥ three 14-day treatment courses that started within the last 6 months.

Approval Duration
All Lines of Business (except Medicare): 14 days

C. Travelers' Diarrhea
1. Re-authorization is not permitted. Members must meet the initial approval criteria. Review initial approval criteria for new cases of travelers' diarrhea unrelated to original medication request.

Approval Duration
All Lines of Business (except Medicare): Not applicable

D. Small Intestinal Bacterial Overgrowth (off-label) (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration
All Lines of Business (except Medicare): 14 days

References

1. Shafran I, Johnson LK. An open-label evaluation of rifaximin in the treatment of active Crohn`s disease. Curr Med Res Opin 2005;21:1165-9. Available at: https://pubmed.ncbi.nlm.nih.gov/16083525/. Accessed November 29, 2024.
2. Prantera C, Lochs H, Campieri M, Scribano ML, Sturniolo GC, et al. Antibiotic treatment of Crohn`s disease: results of a multicentre, double blind, randomized, placebo-controlled trial with rifaximin. Aliment Pharmacol Ther. 2006: 23:1117-25. Available at: https://pubmed.ncbi.nlm.nih.gov/16611272/. Accessed November 29, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Updated initial approval criteria I.A.2 for hepatic encephalopathy in specify lactulose monotherapy. 3. Updated initial approval criteria I.D.3 for SIBO to include failure of systemic antibiotic. 4. Continued therapy criteria II.A.1, B.1, C.1, D.1, E1 was rephrased to "Currently receiving medication that	08/26/2020	09/14/2020

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has been authorized by RxAdvance…". 5. Approval duration was updated to include commercial, Medicaid and HIM plan in initial approval as well as in clinical therapy criteria. 6. References were updated.		
Policy was reviewed: 1. Continued therapy criteria II.A.1, B.1, C.1, D.1, E.1 was rephrased to "Member is curretly...". 2. HIM deleted as per update. 3. Updated initial approval criteria under I.A.3, and I.B.3 4. References were reviewed and updated.	04/12/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.B.3: Updated trial and failure criteria from Failure of any two of the following, each from a different drug class, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced to Failure of at least two of the following (a, b, or c) from different classes, unless contraindicated or clinically significant adverse effects are experienced: a. anti-diarrheal agent (e.g., loperamide); b. antispasmodic (e.g., dicyclomine, hyoscyamine); c. Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine, etc.) 2. Initial Approval Criteria, I.E.3: Updated trial and failure criteria from 3. Failure of metronidazole or ciprofloxacin, unless contraindicated or clinically significant adverse effects are experienced to Failure of at least one (1) (metronidazole or ciprofloxacin), at up to maximal indicated, unless contraindicated or clinically significant adverse effects are experienced. 3. References were reviewed and updated.	1/28/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3b, I.D.3, and I.E.3: Updated to remove "at up to maximally indicated doses".	6/27/2022	7/18/2022

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Policy was reviewed: 1. Initial Approval Criteria, I.A.3.b: Updated prior trial and failure criteria to include "unless contraindicated or clinically significant adverse effects are experienced." 2. Initial Approval Criteria, I.A: Updated approval duration from 6 months to 12 months for Commercial. 3. Initial Approval Criteria, I.B.3.c: Updated prior trial and failure criteria to remove class "Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine, etc.)." 4. Initial Approval Criteria, I.C.3: Updated prior trial and failure criteria to include "1000 mg as a single dose" and to remove drugs "ciprofloxacin, levofloxacin, ofloxacin" 5. Initial Approval Criteria, I.D.3: Updated to remove prior trial and failure criteria to Failure of systemic antibiotic such as ciprofloxacin, norfloxacin, tetracycline, and trimetho-primsulfamethoxazole, unless contraindicated or clinically significant adverse effects are experienced. 6. Initial Approval Criteria, I.E.: Updated to remove approval criteria for Crohn's Disease (off-label). 7. Continued Therapy Approval Criteria, II.E: Updated to remove approval criteria for Crohn's Disease (off-label). 8. References were reviewed and updated.	04/14/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed dose restrictions. 3. Updated approval duration verbiage. 4. Added "Split-fill" to initial criteria approval duration. 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated.	11/29/2024	12/05/2024
Policy was reviewed 1. Split fill removed from IBS-D, TD, and SIBO criteria	4/27/2026	N/A

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