Clinical Policy Title:	rifaximin
Policy Number:	RxA.314
Drug(s) Applied:	Xifaxan®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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. Age ≥ 18 years;
3. 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.
4. Dose does not exceed 1,100 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 6 months

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

1. Diagnosis of IBS-D;
2. Age ≥ 18 years;
3. 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);
4. Dose does not exceed 1,650 mg per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

C. Travelers' Diarrhea (must meet all):

1. Diagnosis of TD;
2. Age ≥ 12 years;
3. Trial and failure of azithromycin 1000 mg as a single dose, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 600 mg per day.

Approval Duration

Commercial: 3 days
Medicaid: 3 days

D. Small Intestinal Bacterial Overgrowth (off-label) (must meet all):
1. Diagnosis of small intestinal bacterial overgrowth (SIBO);
2. Age ≥ 12 years;
3. Dose does not exceed 1,650 mg per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

II. Continued Therapy Approval

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 listed in this policy;
2. Xifaxan® is being used concurrently with lactulose, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1,100 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 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 listed in this policy;
2. Member has not had ≥ three 14-day treatment courses that started within the last 6 months;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 1,650 mg per day.

Approval Duration
Commercial: 14 days
Medicaid: 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
Commercial: Not Applicable
Medicaid: 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 listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,650 mg per day.

Approval Duration
Commercial: Up to 14 days
Medicaid: Up to 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 April 14, 2023.
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 April 14, 2023.

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 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.	08/26/2020	09/14/2020
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:	1/28/2022	04/18/2022

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.		
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
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.	04/14/2023	07/13/2023

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.		
Policy was reviewed.	10/19/2023	10/19/2023