Clinical Policy: Rifaximin (Xifaxan)

Reference Number: PA.CP.PMN.47
Effective Date: 01/18
Last Review Date: 11/16
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Rifaximin (Xifaxan®) is a rifamycin antibacterial.

FDA approved indication
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults
- Travelers' diarrhea (TD) caused by noninvasive strains of E. coli in adult and pediatric patients 12 years of age and older

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness® that Xifaxan is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hepatic Encephalopathy (must meet all)**:**
1. Diagnosis of hepatic encephalopathy;
2. Age ≥ 18 years;
3. Failure of lactulose in the past 30 days, unless member experiences clinically significant adverse effects or has contraindication(s) to lactulose;
4. Request does not exceed 1100 mg/day and health plan approved daily quantity limit. **Recommended regimen is rifaximin (Xifaxan) 550 mg twice daily.**

Approval duration: 6 months

B. Irritable Bowel Syndrome with Diarrhea (must meet all)**:**
1. Diagnosis of irritable bowel syndrome with diarrhea;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):
   a. Failure of ≥ 10 day trial of loperamide at maximum indicated doses, unless member experiences clinically significant adverse effects or has contraindication(s) to loperamide;
   b. Failure of one PDL bile acid sequestrant, unless member has contraindication(s) to all PDL bile acid sequestrants;
4. One of the abovementioned trials occurred within the past 90 days, unless member was unable to complete any trials due to clinically significant adverse effects or contraindication(s) to all of the agents listed in criteria 3a and 3b;
5. Request does not exceed 1650 mg/day and health plan approved daily quantity limit. **Recommended regimen is rifaximin (Xifaxan) 550 mg tablet 3 times a day for 14 days.**

Approval duration: 14 days

C. Travelers' Diarrhea (must meet all)**:**
1. Diagnosis of travelers' diarrhea;
2. Age ≥ 12 years;
3. Failure of one of the following fluoroquinolone regimens, unless member experiences clinically significant adverse effects or has contraindication(s) to these agents:
   a. Ciprofloxacin 500 mg twice daily for 1-3 days;
   b. Levofloxacin 500 mg once daily for 1-3 days;
   c. Ofloxacin 200 mg twice daily for 1-3 days;
4. Failure of azithromycin 1,000 mg given as a single dose, unless member experiences clinically significant adverse effects or has contraindication(s) to azithromycin;
5. Request does not exceed 600 mg/day and health plan approved daily quantity limit. **Recommended regimen is rifaximin (Xifaxan) 200 mg tablet 3 times a day for 3 days.**

Approval duration: 3 days

D. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Hepatic Encephalopathy (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies;
2. Xifaxan is being used concurrently with lactulose, unless member experiences clinically significant adverse effects or has contraindication(s) to lactulose;
3. Request does not exceed 1100 mg/day and health plan approved daily quantity limit. **Recommended regimen is rifaximin (Xifaxan) 550 mg twice daily.**

Approval duration: 12 months

B. Irritable Bowel Syndrome with Diarrhea (IBS-D) (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies;
2. Member has not had ≥ three 14-day treatment courses in the last 6 months;
3. Request does not exceed 1650 mg/day and health plan approved daily quantity limit. **Recommended regimen is rifaximin (Xifaxan) 550 mg tablet 3 times a day for 14 days.**

Approval duration: 14 days

C. Travelers' Diarrhea: may not be renewed as maximum allowed treatment duration is 3 days. Review Initial Approval Criteria for new cases of travelers' diarrhea unrelated to original medication request.

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care policy, PA.LTSS,PHAR.01, applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: duration of request or 6 months (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
HE: hepatic encephalopathy
IBS-D: irritable bowel syndrome with diarrhea
TD: travelers' diarrhea

V. Dosage and Administration

Xifaxan is administered orally with or without food.

Indication	Recommended regimen
HE	One 550 mg tablet 2 times a day
IBS-D	One 550 mg tablet 3 times a day for 14 days
TD	One 200 mg tablet 3 times a day for 3 days

VI. Product Availability

Tablets: 200 mg and 550 mg

VII. References

1. Xifaxan Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals; November 2015. Available at https://www.xifaxan.com/. Accessed September 22, 2016.
2. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline by AASLD-EASL. Hepatology. 2014; 60 (2): 715-735.
3. Weinberg DS, Smalley W, Heidelbaugh JJ, Shahnaz S. American Gastroenterological Association Institute guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology. 2014; 147: 1146-1149.
4. Lacy BE, Chey WD, Lembo AJ. New and emerging treatment options for irritable bowel syndrome. Gastroenterol Hepatol. 2015; 11(4 Suppl 2): 1-19.
5. Hill DR, Ericsson CD, Pearson RD, et al. The practice of travel medicine: guidelines by the Infectious Diseases Society of America. Clin Infect Dis. 2006; 43:1499-1539.

Reviews, Revisions, and Approvals	Date	Approval Date