Washington State Health Care Authority

Antibiotics : Anti-Infective Agents – Oral rifaximin (Xifaxan®)

Medical policy no. 16.00.00.49-2 Effective Date: October 1, 2025

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Rifaximin is a non-absorbable antibiotic that is used for gastrointestinal infections and other conditions involving the gastrointestinal system. Gastrointestinal infections are viral, bacterial, or parasitic infections that cause gastroenteritis, an inflammation of the gastrointestinal tract involving both the stomach and the small intestine. Symptoms include diarrhea, vomiting, and abdominal pain. Rifaximin is utilized in the treatment of bacterial gastrointestinal infections. Rifaximin can also be used for the prophylaxis of hepatic encephalopathy when used together with lactulose.

Medical necessity

Drug	Medical Necessity
rifaximin (Xifaxan®)	Rifaximin for gastrointestinal conditions may be considered medically necessary for patients 20 years of age and younger through Early and Periodic Screening, Diagnostic, and Treatment services (EPSDT) when used for: • Prophylaxis of hepatic encephalopathy • Treatment of irritable bowel syndrome with diarrhea (IBS-D) • Treatment of traveler's diarrhea caused by noninvasive strains of *E. coli*

Clinical policy:

Indication	Clinical Criteria (Initial Approval)
Prophylaxis of hepatic encephalopathy	1. Patient has a history of overt hepatic encephalopathy OR liver cirrhosis; 2. Patient has **ONE** of the following: a. Currently stabilized on and will continue to use lactulose at maximally tolerated dose; **OR**

	b. History of failure of lactulose at a maximally tolerated dose for at least 30 days, or contraindication or intolerance to lactulose; **AND** 3. Patient is greater than or equal to 18 years of age; **AND** 4. Dose less than or equal to 1,100mg per day; **AND** If ALL criteria are met, the request will be approved for 12 months
	Criteria (Reauthorization) 1. Most recent lab value(s) of serum ammonia; **AND** 2. Documentation of an improvement in hepatic encephalopathy, such as any **ONE** of the following: a. improvements in mental status; **OR** b. decrease in hospitalizations or emergency department visits; **OR** c. other predefined clinical criteria as specified by the provider If ALL criteria are met, the request will be approved for 12 months
Irritable bowel syndrome with diarrhea (IBS-D)	**Clinical Criteria (Initial Approval)** 1. Patient has a history of failure, contraindication or intolerance to **TWO** prior therapies for the treatment of IBS-D: a. antidiarrheal (e.g., loperamide); **OR** b. antispasmodics (e.g., dicyclomine); **OR** c. tricyclic antidepressants (e.g., amitriptyline); **AND** 2. Patient is greater than or equal to 18 years of age; **AND** 3. Dose less than or equal to 1,650mg per day for 14 days 4. Patient has not used more than 2 courses of treatment for IBS-D in lifetime If ALL criteria are met, the request will be approved for a 14-day supply.
	Criteria (Reauthorization) 1. Documentation of improvement in IBS-D related symptoms from previous course(s) of treatment; **AND** 2. Documentation with rationale for continued use of rifaximin; **AND** 3. Patient has not used more than 2 courses of treatment for IBS-D in lifetime If ALL criteria are met, the request will be approved for up to 2 more 14-day supplies.
Infectious/traveler's diarrhea, noninvasive strains of E coli	**Clinical Criteria (Initial Approval)** 1. Confirm that this episode (infection) of traveler's diarrhea is caused by non-invasive strains of *E. coli*

	2. Patient has failed prior antibiotic treatment for this episode (defined as no improvement or resolution of symptoms after 5 days of completing regimen) or contraindication or intolerance to TWO of the following: a. Azithromycin; **OR** b. Ciprofloxacin; **OR** c. Levofloxacin; **AND** 3. Culture/sensitivity testing showing antibiotic resistance to all THREE of the following: a. Azithromycin; **OR** b. Ciprofloxacin; **OR** c. Levofloxacin; **AND** 4. Patient has not previously failed rifaximin for current episode or has culture/sensitivity testing showing antibiotic resistance to rifaximin; **AND** 5. Patient is greater than or equal to 12 years of age; **AND** 6. Dose is less than or equal to 600 mg per day for 3 days If ALL criteria are met, the request will be approved for a 3-day supply.
	Criteria (Reauthorization)
	Requests for renewal or extension beyond the authorized amount for rifaximin for the same treatment episode will be denied as not medically necessary, except: 1. when all other treatment options have been ruled out; **AND** 2. culture/sensitivity testing shows no antibiotic resistance to rifaximin

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
rifaximin (XIFAXAN®) 200mg tablet	Infectious/traveler's diarrhea: #9 tablet for 3-day treatment
rifaximin (XIFAXAN®) 550mg tablet	Hepatic encephalopathy: #60 tablets per 30-day supply IBS-D: #42 tablets per 14-day supply

References

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10. Xifaxan (rifaximin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals Inc; January 2018.
11. 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. Available at: http://www.aasld.org/publications/practice-guidelines-0. Accessed January 25, 2017.
12. Bass NM, Mullen KD, Sanyal A, et al. Rifaximin treatment in hepatic encephalopathy. N Engl J Med. 2010; 362:1071-81.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
9/30/2025	10/1/2025	16.00.00.49-2	• Updated to include medical necessity criteria only applies to patients 20 years of age and younger through Early and Periodic Screening, Diagnostic, and Treatment services (EPSDT). As of 10/1/2025 rifaximin (Xifaxan®) is non-covered due to the termination of federal rebate agreement.

Previous policy changes	
Date	**Action and Summary of Changes**
4.30.2025	• Hepatic encephalopathy: Removed documentation of serum ammonia levels. • Note and AHPDL link updated to reflect current language and formatting.
5.31.2019	Hepatic encephalopathy: Removed baseline documentation of predefined clinical criteria as specified by the provider
5.03.2019	New Policy