

Date: <Insert Date>

Payer Name: <Insert Payer Name>

Payer Address: <Insert Plan Address>

Payer Fax Number: <Insert Plan Fax Number>

Attn: <Appeals Department>

To Whom It May Concern:

I am writing on behalf of my patient <Insert Patient Name> to provide additional information supporting medical necessity for treatment with **Xifaxan (rifaximin) 550mg tablets**. Within this letter I am providing my patient's medical history, diagnosis, a description of their previous drug treatment, and a summary of their proposed treatment plan. I have also provided my clinically based rationale supporting the medical necessity of **Xifaxan (rifaximin) 550mg tablets** for my patient.

Patient Information:

Patient's Name		Date of Birth
Patient's Address		
City	State	Zip Code
Member ID #	Policy or Group #	

☐ I need approval for a drug that requires a prior authorization prior to treatment

Medication:

Xifaxan (rifaximin) 550mg tablets:

- ☐ Overt Hepatic Encephalopathy (**OHE**) for reduction in the risk of recurrence: One 550-mg tablet twice daily #60 tablets for 30 days
- ☐ Irritable Bowel Syndrome with Diarrhea (**IBS-D**) in adults: One 550-mg tablet 3 times daily, for 14 days #42 tablets

Date Started:	Expected Length of Therapy: ☐ OHE : ____ months/ ____refills ☐ IBS-D : 14 days (can be refilled up to 2 times)
---------------	--

Diagnosis – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes.

- ☐ **K76.82 (OHE)** Hepatic Encephalopathy ☐ **K58.0 (IBS-D)** Irritable Bowel Syndrome in adults

Related past therapeutic treatment history: (for treatment of the condition(s) requiring the requested drug)

Previous Drug Tried	Dates of Drug Trials	Results of previous drug trials
---------------------	----------------------	---------------------------------

CLINICAL RATIONALE FOR MEDICAL NECESSITY (check all that apply)

☐ Alternate drug(s) contraindicated or previously tried, but with adverse outcome, eg, toxicity, allergy, or therapeutic failure.

☐ Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change.

☐ XIFAXAN earned the highest possible recommendation (GRADE I, A, 1) by the AASLD/EASL as an add-on therapy to lactulose to reduce the risk of OHE recurrence after a patient has a recurrence while on lactulose alone.

☐ Patient is at risk of recurring episode(s) of overt hepatic encephalopathy and rehospitalization due to OHE.

☐ XIFAXAN was given a strong recommendation to treat global IBS-D symptoms, based on a moderate quality of evidence, in the 2020 American College of Gastroenterology (ACG) Clinical guideline on Managing IBS.

☐ Patient is experiencing multiple IBS-D symptoms such as ab pain, diarrhea, and bloating and requires treatment with demonstrated efficacy and safety for each of these.

(List Below):

Based on the information provided, I believe that **Xifaxan (rifaximin) 550mg tablets** are medically necessary for my patient. Please find attached the additional documents that support my clinical decision. If you need additional information for a timely approval, please contact me at <Insert Phone Number>

Sincerely

<Insert Healthcare Provider Name>

<Insert Signature>

Enclosures: Consider including patient medical history, relevant state therapy legislation, notes and product prescribing information which can be found at: [XIFAXAN® \(rifaximin\) for patients with Overt HE and IBS-D | HCP](#)

State Therapy Law Information (www.steptherapy.com)

FOR THE PRESCRIBERS' BACKGROUND INFORMATION:

INDICATIONS

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In clinical studies, the most common adverse reactions for XIFAXAN (alone or in combination with lactulose) were:
 - HE (≥10%): Peripheral edema (17%), constipation (16%), nausea (15%), fatigue (14%), insomnia (14%), ascites (13%), dizziness (13%), urinary tract infection (12%), anemia (10%), and pruritus (10%)
 - IBS-D (≥2%): Nausea (3%), ALT increased (2%)
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at [1-800-321-4576](tel:1-800-321-4576) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) or www.fda.gov/medwatch.

Please [click here](#) for full Prescribing Information.

Xifaxan is a trademark of Salix Pharmaceuticals or its affiliates.

All other trademarks are the property of their respective owners.

© 2025 Salix Pharmaceuticals or its affiliates.

XIF.0190.USA.19V3.0