Prior Authorization Guide for Overt Hepatic Encephalopathy

98% of commercially insured patients have coverage for XIFAXAN[1*]

81% PA approval rate for XIFAXAN in 2020 when submitted through CoverMyMeds

96% of Medicare patients have coverage for XIFAXAN[1*]

90% of eligible, commercially insured patients who had coverage for XIFAXAN paid $10 or less for their prescription when a copay card or eVoucher was applied in 2020[1]

Sometimes a Prior Authorization (PA) is needed once XIFAXAN has been prescribed. When it is, submitting one is simple: follow the directions on the next page.

INDICATION
Xifaxan (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence 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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

**Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.*

For Patients With OHE

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (OHE) recurrence in adults. When a PA is required for XIFAXAN, be sure that all information is included and accurate.

Step 1 – Provide patient and insurance information

Step 2 – Include prescriber information

(eg, practice name, your name, NPI #, DEA/License #)

Step 3 – Provide accurate information, including:

- **Age, diagnosis, dosing**
  Age of patient, twice daily, ***60 tablets*** *with refills*[†]
- **ICD-10 code for OHE**[3*]
  K72.9 *Hepatic failure, unspecified*
  (Have prescriber ***write hepatic encephalopathy next to ICD-10 code*** *on prescription to help with approval.)*
- **Previous therapies tried and failed**[2]
  (eg, lactulose)
- **Rationale for prescribing XIFAXAN**
  (eg, reduction in risk of overt HE recurrence in adults)

Step 4 – Remember your signature and the date

90% PA approval rate in 2020 for OHE[†]

when submitted through CoverMyMeds[1]

- *Being proactive with Prior Authorizations leads to higher approval rates in 2020*[1]

A Letter of Medical Necessity may be needed. If so, it is important to

- Keep it concise
- Submit on practice letterhead
- Include patient name
- Include name of medication *(eg, XIFAXAN 550 mg)*
- Specify diagnosis *(eg, OHE)*
- State your treatment rationale
- Specify duration of treatment *(eg, as long as recommended for OHE)*
- Include your name, signature, and date

[†]If coverage allows refills, write for 180 tablets.

See next page for common reasons PAs are not approved, and ways to help avoid denials.

IMPORTANT SAFETY INFORMATION (continued)

- *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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Common Reasons for PA Denials

REASON FOR DENIAL	CONSIDERATIONS FOR AVOIDING DENIAL
Prior authorization not completed	Double-check PA, fill in missing information, and resubmit
Dosing does not match Indication	Double-check dosing • For OHE: XIFAXAN 550 mg, twice daily, 60 tablets[2]; if coverage allows refills, write for 180 tablets
Invalid diagnosis code	Double-check ICD-10 code and resubmit* • OHE: **K72.9** Hepatic failure, unspecified[3]
Did not try & fail formulary alternative	Include information on why XIFAXAN is necessary and how you expect it to help the patient (eg, reduction in risk of OHE recurrence)
Product is a plan exclusion	Double-check coverage; Medicare excludes certain kinds of drugs, but XIFAXAN is not in those categories
Medication not covered	You can ask insurance plan to reevaluate; XIFAXAN is covered for 98% of commercially insured patients and 96% of Medicare patients[1]*

***The ICD-10 codes and all other patient-access-related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment and applicable ICD-10 Code. Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.**

IMPORTANT SAFETY INFORMATION (continued)

- 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 a clinical study, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- 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 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

References: 1. Data on file. Salix Pharmaceuticals. Bridgewater, NJ. **2.** XIFAXAN [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals. **3.** Centers of Medicare & Medicaid Services. 2021 ICD-10-CM Accessed April 21, 2021. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm.

Salix Pharmaceuticals: 400 Somerset Corporate Blvd., Bridgewater, NJ 08807

Xifaxan® rifaximin 550 mg tablets