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| REQUEST FOR MEDICARE DRUG COVERAGE DETERMINATION |

**Use this form to ask our plan for a coverage determination.** You can also ask for a coverage determination by phone at [insert plan telephone number] or through our website at [insert plan web address]. You, your doctor or prescriber, or your authorized representative can make this request.

**Plan Enrollee**

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| --- | --- |
| Name | Date of birth |
| Street address | City |
| State | ZIP |
| Phone | Member ID # |

If the person making this request isn’t the plan enrollee or prescriber:

| Requestor’s name |
| --- |
| Relationship to plan enrollee |
| Street address (include City, State and ZIP |
| Phone |
| * Submit documentation with this form showing your authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or equivalent). For more information on appointing a representative, contact our plan or call 1-800-MEDICARE.   (1-800-633-4227). TTY users can call 1-877-486-2048. |

| **Name of drug this request is about** (include dosage and quantity information if available)  **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** |
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| Type of Request |
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☐ My drug plan charged me a higher copayment for a drug than it should have

☐ I want to be reimbursed for a covered drug I already paid for out of pocket

☐ I’m asking for prior authorization for a prescribed drug (this request may require supporting information)

For the types of requests listed below, your prescriber MUST provide a statement supporting the request. Your prescriber can complete pages 3 and 4 of this form, “Supporting Information for an Exception Request or Prior Authorization.”

☐I need a drug that’s not on the plan’s list of covered drugs **(formulary exception)**

☐ I’ve been using a drug that was on the plan’s list of covered drugs before, but has been or will be removed during the plan year **(formulary exception)**

☐ I’m asking for an exception to the requirement that I try another drug before I get a prescribed drug **(step therapy/formulary exception)**

☐ I’m asking for an exception to the plan’s limit on the number of pills **(quantity limit)** I can get so that I can get the number of pills prescribed to me (formulary exception)

☐ I’m asking for an exception to the plan’s prior authorization rules that must be met before I get a prescribed drug (Prior Authorization/formulary exception).

☐ My drug plan charges a higher copayment for a prescribed drug than it charges for another drug that treats my condition, and I want to pay the lower copayment **(tiering exception)**

☐ I’ve been using a drug that was on a lower copayment tier before, but has or will be moved to a higher copayment tier **(tiering exception)**

Additional information we should consider *(submit any supporting documents with this form)*:

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| Do you need an expedited decision? |

If you or your prescriber believe that waiting 72 hours for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 72 hours could seriously harm your health, we’ll automatically give you a decision within 24 hours. If you don’t get your prescriber's support for an expedited request, we’ll decide if your case requires a fast decision. (You can’t ask for an expedited decision if you’re asking us to pay you back for a drug you already received.)

☐ **YES, I need a decision within 24 hours.** If you have a supporting statement from your prescriber, attach it to this request.

| Signature: | Date: |
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**How to submit this form**

Submit this form and any supporting information by mail or fax:

Address: Fax Number:

<Insert Payer Name> <Insert Plan Fax Number>

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| Supporting Information for an Exception Request or Prior Authorization  To be completed by the prescriber |

**☐ REQUEST FOR EXPEDITED REVIEW: By checking this box and signing below, I certify that applying the 72 hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function.**

**Prescriber Information**

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| Name |
| Street Address (Include City, State and ZIP |
| Office phone |
| Fax |
| Signature Date |

**Diagnosis and Medical Information**

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| Medication: **Xifaxan (rifaximin)550mg tablets** | Strength and route of administration: **550mg tablets, orally** | |
| Frequency: Select one  **☐ OHE:** **One 550-mg tablet twice daily #60 tablets for 30 days**  **☐ IBS-D: One 550-mg tablet 3 times daily, for 14 days #42 tablets** | Date started: \_\_\_\_ / \_\_\_\_ /\_\_\_\_  **☐ NEW START** | |
| Expected length of therapy:  **☐ OHE:** **30 days/indefinite**  **☐ IBS-D: 14 days** | Quantity per 30 days:  **☐ OHE:** **#60 tablets**  **☐ IBS-D: #42 tablets** | |
| Height/Weight: | Drug allergies: | |
| **DIAGNOSIS – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes**  **(**If the condition being treated with the requested drug is a symptom e.g. anorexia, weight loss, shortness of breath, chest pain, nausea, etc., provide the diagnosis causing the symptom(s) if known)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Ex: Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults**  **Ex: Irritable Bowel Syndrome with Diarrhea (IBS-D) in adults** | | **ICD-10 Code(s)**  **Ex: OHE: K76.82**  **Ex: IBS-D: K58.0** |
| **Other RELAVENT DIAGNOSES:** | | **ICD-10 Code(s)** |

**DRUG HISTORY: (for treatment of the condition(s) requiring the requested drug)**

| **DRUGS TRIED**  (if quantity limit is an issue, list unit dose/total daily dose tried) | **DATES of Drug Trials** | **RESULTS of previous drug trials**  **FAILURE vs INTOLERANCE (explain)** |
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| **What is the enrollee’s current drug regimen for the condition(s) requiring the requested drug?** |

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| **DRUG SAFETY** |
| Any **FDA NOTED CONTRAINDICATIONS** to the requested drug? **☐ YES ☐ NO** |
| Any concern for a **DRUG INTERACTION** when adding the requested drug to the enrollee’s current drug regimen?  **☐ YES ☐ NO** |
| If the answer to either of the questions above is yes, please 1) explain issue, 2) discuss the benefits vs potential risks despite the noted concern, and 3) monitoring plan to ensure safety |

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| **HIGH RISK MANAGEMENT OF DRUGS IN THE ELDERLY** |
| If the enrollee is over the age of 65, do you feel that the benefits of treatment with the requested drug outweigh the potential risks in this elderly patient? **☐ YES ☐ NO** |

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| **OPIOIDS – (answer these 4 questions if the requested drug is an opioid)** |
| What is the daily cumulative Morphine Equivalent Dose **(MED)**? **mg/day** |
| Are you aware of other opioid prescribers for this enrollee? **☐ YES ☐ NO**  If so, please explain. |
| |  |  | | --- | --- | | Is the stated daily MED dose noted medically necessary? **☐ YES ☐ NO** |  | | Would a lower total daily MED dose be insufficient to control the enrollee’s pain? **☐ YES ☐ NO** |  | |

**RATIONALE FOR REQUEST**

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| **☐ Alternate drug(s) previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure** [If not noted in the DRUG HISTORY section, specify below: (1) Drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure, list maximum dose and length of therapy for drug(s) trialed]  **☐Alternative drug(s) contraindicated, would not be as effective or likely to cause adverse outcome.** A specific explanation why alternative drug(s) would not be as effective or anticipated significant adverse clinical outcome and why this outcome would be expected is required. If contraindication(s), list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated  **☐ Patient would suffer adverse effects if he or she were required to satisfy the prior authorization requirement.** A specific explanation of any anticipated significant adverse clinical outcome and why this outcome would be expected is required.  **☐ Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change** A specific explanation of any anticipated significant adverse clinical outcome and why this outcome would be expected is required – e.g. the condition has been difficult to control (many drugs tried, multiple drugs required to control condition), the patient had a significant adverse outcome when the condition was not controlled previously (e.g. hospitalization or frequent acute medical visits, heart attack, stroke, falls, significant limitation of functional status, undue pain and suffering),etc.  **☐ Request for formulary tier exception** If not noted in the DRUG HISTORY section, specify below: (1) formulary or preferred drug(s) tried and results of drug trial(s) (2) if adverse outcome, list drug(s) and adverse outcome for each, (3) if therapeutic failure/not as effective as requested drug, list maximum dose and length of therapy for drug(s) trialed, (4) if contraindication(s), list specific reason why preferred drug(s)/other formulary drug(s) are contraindicated]  **☐ Medical need for different dosage form and/or higher dosage** [Specify below: (1) Dosage form(s) and/or dosage(s) tried and outcome of drug trial(s); (2) explain medical reason (3) include why less frequent dosing with a higher strength is not an option – if a higher strength exists]  **☐ Other** (explain below)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**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](https://shared.salix.com/shared/pi/xifaxan550-pi.pdf)**for full Prescribing Information.**

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