RIFAXIMIN

Generic	Brand	HICL	GCN	Exception/Other
RIFAXIMIN	XIFAXAN		28530 93749	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

1. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The medication is being prescribed by a hepatologist
   - The patient had a trial of lactulose or is currently on lactulose monotherapy

   If yes, **approve for 12 months for Xifaxan 550mg (GPID 28530) with a quantity limit of #2 tablets per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The medication is being prescribed by a gastroenterologist
   - The patient had a trial of or contraindication to tricyclic anti-depressants or dicyclomine

   If yes, **approve for 12 weeks for Xifaxan 550mg (GPID 28530) for 1 fill of #42 tablets.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **RIFAXIMIN 550mg TABLETS (Xifaxan)** requires use for the reduction in risk of overt hepatic encephalopathy (HE) recurrence or for the diagnosis of irritable bowel syndrome with diarrhea (IBS-D). In addition, the following criteria must be met:
   For the reduction in risk of overt hepatic encephalopathy (HE) recurrence, approval requires:
   - The patient is 18 years of age or older
   - The medication is being prescribed by a hepatologist
   - The patient had a trial of lactulose or is currently on lactulose monotherapy

   For the diagnosis of irritable bowel syndrome with diarrhea (IBS-D), approval requires:
   - The patient is 18 years of age or older
   - The medication is being prescribed by a gastroenterologist
   - The patient had a trial of or contraindication to tricyclic anti-depressants or dicyclomine

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RIFAXIMIN

INITIAL CRITERIA (CONTINUED)

XIFAXAN 200MG TABLETS

1. Does the patient have a diagnosis of travelers' diarrhea (TD) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   If yes, **approve for 3 days for Xifaxan 200 mg (GPID 93749) for 1 fill of #9 tablets.**
   If no, continue to #2.

2. Is the request for the treatment of overt hepatic encephalopathy (HE) **AND** the patient meets the following criterion?
   - The requested medication will be used in combination with lactulose

   If yes, **approve for 10 days for Xifaxan 200 mg (GPID 93749) with a quantity limit of #6 tablets per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of *Clostridium difficile* infection (CDI) and meet **ALL** of the following criteria?
   - The patient has had at least one previous occurrence of *Clostridium difficile* infection
   - The requested medication will be used in combination with vancomycin
   - Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes, **approve for 20 days for Xifaxan 200 mg (GPID 93749) with a quantity limit of #6 tablets per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **RIFAXIMIN 200MG TABLETS (Xifaxan)** requires a diagnosis of travelers' diarrhea (TD), *Clostridium difficile* infection (CDI) or for the treatment of overt hepatic encephalopathy (HE). In addition, the following criteria must be met:
   For the diagnosis of traveler's diarrhea (TD), approval requires:
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   For the treatment of overt hepatic encephalopathy (HE), approval requires:
   - The requested medication will be used in combination with lactulose

   For the diagnosis of *Clostridium difficile* infection (CDI), approval requires:
   - The patient has had at least one previous occurrence of *Clostridium difficile* infection
   - The requested medication will be used in combination with vancomycin
   - Therapy is prescribed by or in consultation with an infectious disease specialist

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RIFAXIMIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for renewal of Xifaxan 550mg tablet?

   If yes, continue to #2.
   If no, please refer to initial criteria above for Xifaxan 200mg request.

2. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence?

   If yes, **approve for 12 months for Xifaxan 550mg (GPID 28530) with a quantity limit of #2 tablets per day.**
   If no, continue to 3.

3. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - At least 10 weeks have passed since the last treatment course of rifaximin
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months for Xifaxan 550mg (GPID 28530) for up to 2 fills of #42 tablets each fill, separated by at least 12 weeks (total of 2 fills in 12 months).**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **RIFAXIMIN 550MG TABLETS (Xifaxan)** requires use for the reduction in risk of overt hepatic encephalopathy (HE) recurrence or the diagnosis of irritable bowel syndrome with diarrhea (IBS-D) for renewal. In addition, the following criteria must be met:
   - **For the treatment of irritable bowel syndrome with diarrhea (IBS-D), approval requires:**
     - At least 10 weeks have passed since the last treatment course of rifaximin
     - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
     - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

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RATIONALE

For further information, please refer to the Prescribing Information for Xifaxan.

REFERENCES

- Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. January 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/19
Created: 02/05
Client Approval: 03/19
P&T Approval: 01/19