STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIFAXIMIN	XIFAXAN		28530 93749	GPI-14 (16000049000340) (16000049000320)	

**** 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
   - Therapy is prescribed by or in consultation with a hepatologist
   - The patient had a trial of lactulose or is currently on lactulose monotherapy

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 with a quantity limit of #2 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
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to tricyclic anti-depressants or dicyclomine

   If yes, **approve for 8 weeks for Xifaxan 550mg by GPID or GPI-14 for 1 fill of #42.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 550MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor)
   3. You have previously tried lactulose or you are currently taking lactulose monotherapy (drug used alone for treatment)

C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to tricyclic anti-depressants (such as amitriptyline, nortriptyline, etc.) or dicyclomine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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 200mg by GPID or GPI-14 for 1 fill of #9.**
   If no, continue to #2.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 200MG TABLETS (CONTINUED)

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 200mg by GPID or GPI-14 with a quantity limit of #6 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 200mg by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIFAXIMIN (Xifaxan 200 mg tablets)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Travelers' diarrhea
      2. *Clostridium difficile* infection (a type of bacterial infection)
      3. Treatment of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)
   B. **If you have traveler's diarrhea, approval also requires:**
      1. You are 12 years of age or older
      2. You had a trial of or contraindication (harmful for) to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin
   C. **For the treatment of overt hepatic encephalopathy, approval also requires:**
      1. The requested medication will be used in combination with lactulose
   D. **If you have *Clostridium difficile* infection, approval also requires:**
      1. You had at least one previous occurrence of *Clostridium difficile* infection
      2. The requested medication will be used in combination with vancomycin
      3. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

   (Initial Xifaxan 200mg tablets denial text continued on next page)

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 200MG TABLETS (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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 by GPID or GPI-14 with a quantity limit of #2 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 6 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 by GPID or GPI-14 for up to 2 fills of #42 each fill, separated by at least 8 weeks (total of 2 fills in 12 months).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIFAXIMIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Reduction of risk of overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage) recurrence
   2. Irritable bowel syndrome with diarrhea (IBS-D: a type of bowel disease)

B. **If you have irritable bowel syndrome with diarrhea, renewal also requires:**
   1. At least 6 weeks have passed since your last treatment course of rifaximin
   2. You have experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have 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)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 02/05
Client Approval: 02/22
P&T Approval: 01/22