Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Xifaxan (rifaximin)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2010 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Xifaxan (rifaximin).

Xifaxan (rifaximin) 200mg is indicated for the treatment of patients >12 years of age with travelers' diarrhea caused by non-invasive strains of Escherichia coli.

Xifaxan (rifaximin) 550mg is indicated for the reduction in risk of overt Hepatic Encephalopathy (HE) recurrence in patients 18 years of age or older and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to

make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Xifaxan (rifaximin), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Reduction of risk of hepatic encephalopathy (HE) recurrence in adults**
   - Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist
   - Must have a diagnosis of hepatic encephalopathy
   - Must be age 18 years or older
   - Must have had a previous trial and failure of lactulose

2. **Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults**
   - Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist
   - Must be age 18 years or older
   - Must have a diagnosis of diarrhea-predominant IBS with chronic IBS symptoms (generally lasting 6 months or longer). Chart documentation describing how diagnosis was confirmed (e.g. duration of symptoms, types of symptoms, exclusion of other diagnoses and causes of diarrhea, etc.) is required.
   - Must have an adequate trial and failure of loperamide or antispasmodics (such as dicyclomine or hyoscyamine) with inadequate response or significant side effect/toxicity or have a contraindication to these therapies

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at a 2-week or 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

- For IBS-D: Reauthorizations will only be granted at two week intervals if the member has had a recurrence of IBS-D symptoms after a successful treatment course based upon

chart documentation from the provider.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Hepatic encephalopathy: up to 1 year • IBS-D: up to 2 weeks
Reauthorization	• Hepatic encephalopathy: up to 1 year • IBS-D: up to 2 weeks (maximum of 2 retreatment courses per lifetime)
Quantity Level Limit	
200mg	9 tablets per prescription
550mg	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Xifaxan [package insert]. Morrisville, NC: Salix Pharmaceuticals; May 2015
2. Bass NM, Mullen, KD, Sanyal A, et al. Rifaximin Treatment in Hepatic Encephalopathy. NEJM 2010; 12: 1071-1081.
3. Pimental M, et al. Rifaximin Therapy for Patients with Irritable Bowel Syndrome without Constipation. N Engl J Med. 2011; 364:22-32.
4. Spiller R, Aziz Q, Creed F, et al. Guidelines on the irritable bowel syndrome: mechanisms and practical management. Gut. 2007;56(12):1770-98.
5. Ford A, Moayyedi P, Lacy B, et al. Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. AM J Gastroenterol. 2014: 109.S2.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Criteria Update	*04/17*