Pharmacy Medical Necessity Guidelines: Xifaxan

Effective: December 17, 2018

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Xifaxan (rifaximin) 200 mg tablets are indicated for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older.

Xifaxan (rifaximin) should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *E. coli*.

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

In trials of Xifaxan (rifaximin) for hepatic encephalopathy, 91% of the patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxin (rifaximin) has not been studied in patients with Model for End-Stage Liver Disease scores > 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction.

Xifaxan (rifaximin) 550 mg tablets are also indicated for the treatment of irritable bowel syndrome with diarrhea in adults.

The recommended dosage regimens for each indication are listed in the table below.

Condition	Recommended Dosage Regimens
Travelers' Diarrhea	One 200 mg tablet 3 times per day for 3 days
Hepatic Encephalopathy	One 550 mg tablet twice daily
IBS-D	One 550 mg tablet 3 times per day for 14 days. *Patients who experience recurrent can be retreated up to 2 times with the same regimen.*

COVERAGE GUIDELINES

The plan may authorize coverage of Xifaxan (rifaximin) for Members when all the following criteria are met:

For Traveler's Diarrhea

1. The Member had a documented diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli*

AND

2. The Member has had an inadequate response, intolerance, or contraindication to ciprofloxacin and azithromycin

For Hepatic Encephalopathy

1. The Member has a physician-documented diagnosis of hepatic encephalopathy

AND

2. The Member had an inadequate response, intolerance, or contraindication to lactulose

For Inflammatory Bowel Syndrome with Diarrhea (IBS-D)

1. The Member has a diagnosis of diarrhea predominant irritable bowel syndrome (IBS-D)

AND

2. The Member has had an inadequate response, intolerance, or contraindication to three of the following generic agents: bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, tricyclic antidepressant

LIMITATIONS

1. Xifaxin (rifaximin) will not be covered in the following instances:
    a. Treatment of diarrhea caused by pathogens other than *E. coli*
    b. Treatment of diarrhea complicated by fever or bloody stools
    c. Treatment of irritable bowel syndrome with constipation
    d. Prevention of traveler's diarrhea
2. For traveler's diarrhea, coverage is limited to a 3-day course of therapy (9 tablets) of the 200 mg tablets in any 30-day period
3. For Hepatic Encephalopathy, coverage is limited to 60 tablets per 30 days of the 550 mg tablets
4. For Irritable Bowel Syndrome with Diarrhea (IBS-D), coverage will be limited to one treatment cycle. Subsequent authorizations will require clinical documentation of recurrence from the provider. Xifaxan (rifaximin) for the treatment of IBS-D will only be authorized up to a maximum of three treatment cycles.
5. Duration of coverage for non-FDA-approved indications that have been deemed medically necessary will be determined based on the dosing and length of treatment recommended by compendia for the requested indication. Subsequent approved for non-FDA approved indications will be reviewed on a case by case basis.

CODES

None

REFERENCES

1. Xifaxan (rifaximin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; January 2018.
2. Wald A. Treatment of irritable bowel syndrome in adults. UpToDate. Available at www.uptodate.com. Accessed 1 May 2017.
3. Wanke CA. Travelers' diarrhea: clinical manifestations, diagnosis, and treatment. UpToDate. Available at: www.uptodate.com. Accessed 1 May 2017.

APPROVAL HISTORY

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 11, 2018: Administrative changes made to template.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.