Pharmacy Medical Necessity Guidelines: Xifaxan® (rifaximin)

Effective: January 1, 2017

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

Fax Numbers:

Tufts Health Plan Commercial Plans
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan

Tufts Health Freedom Plan products
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

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 adults 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 the 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. Xifaxan (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.

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 has a documented diagnosis of traveler’s diarrhea caused by noninvasive strains of Escherichia coli

For Hepatic Encephalopathy
1. The member has a physician-documented diagnosis of hepatic encephalopathy

AND

2. The member has had an inadequate response or has a contraindication to lactulose (Constulose, Duphalac, Enulose, Generlac)

For Inflammatory Bowel Disease
1. The member has a documented diagnosis of Inflammatory Bowel Disease (IBD)

AND

2. The member has failed to respond to or has a contraindication to standard antibiotic treatment (e.g., ciprofloxacin [Cipro®], metronidazole [Flagyl®])
For Irritable Bowel Syndrome with Diarrhea (IBS-D)

1. The member has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

LIMITATIONS

1. Xifaxan (rifaximin) would not be covered in the following instances:
   - Treatment of diarrhea caused by pathogens other than *E. coli*
   - Treatment of diarrhea complicated by fever or bloody stools
   - Treatment of Irritable Bowel Syndrome with constipation
   - 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 approvals for non-FDA-approved indications will be reviewed on a case by case basis.

CODES

None

REFERENCES


APPROVAL HISTORY

August 8, 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 10, 2007: Added limitation "Pharmacy Coverage Guidelines for Xifaxan (rifaximin) apply to the Tufts Health Plan Generic Focused Formulary only."
- September 11, 2007: Removed limitation "Pharmacy Coverage Guidelines for Xifaxan (rifaximin) apply to the Tufts Health Plan Generic Focused Formulary only." Added reference table outlining applicable Tufts Health Plan products.
- July 8, 2008: Added coverage criteria for the diagnosis of hepatic encephalopathy. Added coverage criteria for the diagnosis of Inflammatory Bowel Disease (IBD). Added limitation, that Xifaxan will not be covered for the treatment of bacterial overgrowth. Removed limitation that Xifaxan would not be covered for the treatment of hepatic encephalopathy. Clarified limitation, that Xifaxan coverage is limited to a 3-day course of therapy (9 tablets) in any 30-day period for traveler’s diarrhea.
- July 14, 2009: No changes
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- July 13, 2010: Removed, "Rifaximin tablets are indicated for the treatment of traveler’s diarrhea caused by noninvasive strains of *E.coli* in adults and adolescents 12 years of age or older at a dose of 200 mg 3 times a daily for 3 days. Rifaximin was not found to be effective in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *E.coli*. Rifaximin is not effective and should not be used for the treatment of traveler’s diarrhea caused by *Campylobacter jejuni* and has not been proven effective in traveler’s diarrhea caused by *Shigella* spp. and *Salmonella* spp." Added FDA-approved indications for rifaximin 200 mg and 550 mg tablets. Removed, “The member must be 12 years of age or older” for Traveller’s diarrhea indication. Under Hepatic Encephalopathy: Removed, “The member has failed to respond to or has a contraindication to lactulose (Constulose, Duphalac, Enulose, Generlac); replaced with “The
member has had an inadequate response or contraindication to lactulose (Constulose, Duphalac,
Enulose, Generlac). Clarified the limitation for Travelers diarrhea that it applies to the 200 mg
strength. Added a limitation for Hepatic encephalopathy that “coverage is limited to a 30-day
supply (60 tablets) of the 550 mg tablets
• May 10, 2011: Removed the overview section and replaced with FDA-approved indications.
  Removed the limitation on Bacterial Overgrowth Syndrome. Added limitation of Irritable Bowel
  Syndrome.
• March 13, 2012: No changes
• February 12, 2013: No changes
• February 11, 2014: No changes
• February 10, 2015: No changes
• October 6, 2015: Added criteria and limitations for new indication to treat irritable bowel
  syndrome with diarrhea.
• January 1, 2016: Administrative change to rebranded template.
• September 13, 2016: Added limitation #5 to clarify the duration of approval for off-label use:
  “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 approvals for non-FDA-approved indications
  will be reviewed on a case by case basis.”

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. They are used in conjunction with a member’s benefit document and in
coordination with the member’s physician(s). 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.
This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan
members or to certain delegated service arrangements. Unless otherwise noted in the member’s
benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity
Guidelines do not apply to CareLinkSM members. For self-insured plans, drug coverage may vary
depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline
and a self-insured member’s benefit document, the provisions of the benefit document will govern.
Applicable state or federal mandates will take precedence.
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior
Authorization Criteria.
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.