

## Xifaxan (rifaximin)\_Aemcolo (rifamycin) Policy Number: C4964-C

**CRITERIA EFFECTIVE DATES:**

| ORIGINAL EFFECTIVE DATE | LAST REVIEWED DATE | NEXT REVIEW DATE           |
|-------------------------|--------------------|----------------------------|
| 6/13/2018               | 07/03/2019         | 07/03/2020                 |
| J CODE                  | TYPE OF CRITERIA   | LAST P&T APPROVAL/VERSION  |
| NA                      | RxPA               | Q3 2019<br>20190828C4964-C |

**PRODUCTS AFFECTED:**

Xifaxan (rifaximin), Aemcolo (rifamycin)

**DRUG CLASS:**

Antiinfectives: Rifamycin class

**ROUTE OF ADMINISTRATION:**

Oral

**PLACE OF SERVICE:**

Retail Pharmacy

The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

**AVAILABLE DOSAGE FORMS:**

Xifaxan 200mg tablet (30/bottle and 100/bottle), 550mg tablet (60/bottle), Aemcolo TBEC 194MG (12/package and 36/package)

**FDA-APPROVED USES:**

Xifaxan (rifaximin): Treatment of patients 12 years of age and older with travelers' diarrhea (TD) caused by noninvasive strains of E.coli, Reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients > 18 years of age, Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults  
 Aemcolo (rifamycin): Travelers' diarrhea caused by noninvasive strains of E. coli in adults

**COMPENDIAL APPROVED OFF-LABELED USES:** None

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:** Hepatic Encephalopathy, Irritable Bowel Syndrome with diarrhea (IBS-D), Traveler's diarrhea

**REQUIRED MEDICAL INFORMATION:**

**A. HEPATIC ENCEPHALOPATHY-XIFAXAN ONLY:**

1. Documentation of a diagnosis of hepatic encephalopathy  
AND
2. Documentation of a trial/failure or contraindication of lactulose

**B. IRRITABLE BOWEL SYNDROME WITH DIARRHEA (ISB-D)- XIFAXAN ONLY:**

1. Documentation of 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.

AND

2. Documentation of an adequate trial and failure of loperamide AND antispasmodics AND bile acid sequestrants (such as dicyclomine or hyoscyamine) with inadequate response or significant side effect/toxicity or have a contraindication to these therapies

#### C. TRAVELERS DIARRHEA:

1. Diagnosis of moderate (diarrhea that is distressing or interferes with planned activities) travelers' diarrhea  
AND
2. Documentation of a history of failure, contraindication or intolerance to one or more of the following: Azithromycin (generic Zithromax), Ciprofloxacin (generic Cipro), Levofloxacin (generic Levaquin), Ofloxacin (generic Floxin)

#### DURATION OF APPROVAL:

Hepatic Encephalopathy: Initial authorization: 12months, Continuation of Therapy: 12 months  
Irritable Bowel Syndrome with diarrhea (IBS-D): Initial authorization: 14 days, Continuation of Therapy: Patients experiencing a recurrence of symptoms may receive the same 14-day dosing regimen up to 2 additional times (maximum of 3 total treatment cycles per plan year)  
Travelers diarrhea: Initial authorization: 1 fill of 9 tablets (3 days) , Continuation of Therapy: NA

#### QUANTITY:

Xifaxan (rifaximin)

Hepatic Encephalopathy – 60 tabs/30 days of 550mg tabs

Irritable Bowel Syndrome with diarrhea (IBS-D) – 42 tabs/14 days of 550mg tabs

Traveler's diarrhea – 9 tabs/3 days of 200mg tabs

Aemcolo (rifamycin) Travelers diarrhea –12 tabs/3 days

#### PRESCRIBER REQUIREMENTS:

None specified

#### AGE RESTRICTIONS:

Xifaxan (Travelers Diarrhea): 12 years of age and older, Hepatic Encephalopathy: 18 years of age and older

Aemcolo: 18 years of age and older

#### GENDER:

Male and female

#### CONTINUATION OF THERAPY:

##### A. HEPATIC ENCEPHALOPATHY:

1. Documentation of positive clinical benefit (decreas in fasting serum ammonia level from baseline or improvement in patient's mental status)

##### B. IRRITABLE BOWEL SYNDROME WITH DIARRHEA (ISB-D)

1. Documentation of positive clinical benefit from historical use of Xifaxan (rifaximin)  
AND
2. Patient has not had  $\geq 3$  (14) day treatment cycles per plan year.

##### C. TRAVELERS DIARRHEA:

1. NA, New Initial Authorization required

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Xifaxan (rifaximin) and Aemcolo (rifamycin) that are not an FDA-approved indication or not included in this policy are considered not medically necessary. This is subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

**OTHER SPECIAL CONSIDERATIONS:** None**BACKGROUND:**

Travelers' diarrhea is an infectious illness, caused by a variety of bacterial, viral, and parasitic organisms, although bacterial pathogens are the most frequent cause in acute cases. Travelers' diarrhea is the most common travel-related illness, affecting an estimated 10 to 40 percent of travelers worldwide each year. Travelers' diarrhea is defined by having three or more unformed stools in 24 hours, in a person who is traveling. The highest-risk destinations are in most of Asia as well as the Middle East, Africa, Mexico, and Central and South America. Episodes of travelers' diarrhea are nearly always benign and self-limited, but the dehydration that can complicate an episode may be severe and pose a greater health hazard than the infection itself. Epidemiology Risk varies considerably based on destination of travel. The bacterial, viral and parasitic organisms that cause travelers' diarrhea are most often transmitted by food and water, thus risk of travelers' diarrhea is the highest in regions where sanitation and hygienic practices are poor. The risk of travelers' diarrhea also varies with the season of the year, with a higher risk during warmer and wetter seasons. Prevention The most important strategy to prevent travelers' diarrhea is prudent selection of food and drink while traveling. Water purification can be used if sanitary water is not otherwise available. Prophylactic medications (mainly antibiotics) are generally not indicated although may be useful for select travelers for whom an episode of diarrhea could have severe consequences.

**APPENDIX:** None**REFERENCES:**

1. Xifaxan (rifaximin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals Inc; January 2018.
2. Aemcolo (rifamycin) [prescribing information]. San Diego, CA; Aries Pharmaceuticals Inc: November 2018.
3. Bass NM, Mullen, KD, Sanyal A, et al. Rifaximin Treatment in Hepatic Encephalopathy. *NEJM* 2010;12: 1071-1081.
4. Pimental M, et al. Rifaximin Therapy for Patients with Irritable Bowel Syndrome without Constipation. *N Engl J Med.* 2011; 364:22-32.
5. Spiller R, Aziz Q, Creed F, et al. Guidelines on the irritable bowel syndrome: mechanisms and practical management. *Gut.* 2007;56(12):1770-98.
6. 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
7. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. *J Travel Med* 2017;24(1):S57-74.
8. LaRocque R and Harris JB. Travelers' diarrhea: Clinical manifestations, diagnosis, and treatment UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>

9. Rifaximin therapy for patients with irritable bowel syndrome without constipation. AUPimentel M, Lembo A, Chey WD, Zakko S, Ringel Y, Yu J, Mareya SM, Shaw AL, Bortey E, Forbes WP, TARGET Study Group *SON Engl J Med.* 2011;364(1):22