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Last P&T Approval/Version: 07/31/2024
Next Review Due By: 07/2025
Policy Number: C4964-C

Xifaxan (rifaximin), Aemcolo (rifamycin)

PRODUCTS AFFECTED

Xifaxan (rifaximin), Aemcolo (rifamycin)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Hepatic Encephalopathy, Irritable Bowel Syndrome with diarrhea (IBS-D), Traveler's diarrhea, Small intestinal bacterial overgrowth (SIBO)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. HEPATIC ENCEPHALOPATHY (XIFAXAN ONLY):
   1. Documentation of a diagnosis of hepatic encephalopathy
      AND

2. Documentation of insufficient response to lactulose and will be used in combination OR member has serious side effects or contraindication to lactulose

B. IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) [XIFAXAN ONLY]:
   1. Documentation of a diagnosis of diarrhea-predominant IBS with chronic IBS symptoms (generally lasting 6 months or longer)
      AND
   2. Prescriber attests that other causes of diarrhea have been ruled out
      AND
   3. Documentation of an adequate trial and failure of loperamide AND antispasmodics (such as dicyclomine or hyoscyamine) AND bile acid sequestrants (such as cholestyramine or colestipol) with inadequate response or significant side effect/toxicity or have a contraindication to these therapies

C. TRAVELERS DIARRHEA:
   1. Diagnosis of travelers' diarrhea with moderate diarrhea that is distressing or interferes with planned activities
      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)

D. CROHN'S DISEASE (XIFAXAN ONLY):
   1. Documented diagnosis of Crohn's disease
      AND
   2. Documentation member has symptoms of moderately active disease (e.g., fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia)

E. SMALL INTESTINAL BACTERIAL OVERGROWTH (SIBO) [XIFAXAN ONLY]:
   1. Documented diagnosis of small intestinal bacterial overgrowth (SIBO)
      AND
   2. Documentation diagnosis was confirmed by breath testing
      AND
   3. Documentation member is symptomatic (e.g., nausea, bloating, flatulence, abdominal distension, abdominal cramping, abdominal pain, diarrhea, constipation, steatorrhea, weight loss, anemia, deficiencies in fat soluble vitamins, mucosal inflammation of the small bowel)
      AND
   4. Documentation of treatment failure, serious side effects, or clinical contraindication to ONE of the following antibiotic therapies: amoxicillin-clavulanate, ciprofloxacin, doxycycline, metronidazole, neomycin, tetracycline, trimethoprim-sulfamethoxazole

CONTINUATION OF THERAPY:

A. HEPATIC ENCEPHALOPATHY (XIFAXAN ONLY):
   1. Prescriber attests to positive clinical benefit (decrease in fasting serum ammonia level from baseline or improvement in member's mental status)

B. IRRITABLE BOWEL SYNDROME WITH DIARRHEA (ISB-D) [XIFAXAN ONLY]:
   1. Documentation of positive clinical benefit from historical use of Xifaxan (rifaximin)
      AND
   2. Member has not had > 3 (14) day treatment cycles per plan year.

C. TRAVELERS DIARRHEA:
   1. NA, New Initial Authorization required

D. CROHN'S DISEASE (XIFAXAN ONLY):
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND
   3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., fever, weight loss, abdominal pain and tenderness, intermittent nausea or vomiting, or anemia)

E. SMALL INTESTINAL BACTERIAL OVERGROWTH (SIBO) [XIFAXAN ONLY]:
   1. NA, Use Initial Authorization criteria

DURATION OF APPROVAL:
Hepatic Encephalopathy: Initial authorization: 12 months, Continuation of Therapy: 12 months
Irritable Bowel Syndrome with diarrhea (IBS-D): Initial authorization: 14 days, Continuation of Therapy: Members 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
Crohn's Disease: Initial authorization: 3 months, Continuation of therapy: 12 months
SIBO: Initial authorization: 28 days, Continuation of therapy: NA

PRESCRIBER REQUIREMENTS:
None specified

AGE RESTRICTIONS:
Xifaxan (Travelers Diarrhea): 12 years of age and older,
Hepatic Encephalopathy, Irritable bowel syndrome with diarrhea, Crohn's Disease, SIBO, Aemcolo (Travelers Diarrhea): 18 years of age and older

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
Crohn's Disease: 800mg twice daily [240 tablets/30 days of 200mg tabs]
SIBO: 550mg three times per day

Aemcolo (rifamycin):
Travelers' diarrhea: 12 tabs/3 days

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Anti-infectives Agents - Misc

FDA-APPROVED USES:
Xifaxan (rifaximin) indicated for:

- Treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older
  Limitations of Use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Aemcolo (rifamycin) indicated for the treatment of travelers' diarrhea caused by noninvasive strains of E. coli in adults
Limitations of Use: Aemcolo is not recommended for use in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli.

COMPENDIAL APPROVED OFF-LABELED USES:
Moderate to active Crohn's disease, Treatment of hepatic encephalopathy, SIBO in adults

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Xifaxan (rifaximin) and Aemcolo (rifamycin) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy Contraindications to Xifaxan (rifaximin) and Aemcolo (rifamycin) include: known hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components of the requested agent.

OTHER SPECIAL CONSIDERATIONS:
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Aemcolo and other antibacterial drugs, Aemcolo should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Aemcolo TBEC 194MG
Xifaxan TABS 200MG, 550MG

REFERENCES

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2. Aemcolo (rifamycin) [prescribing information]. San Diego, CA; Aries Pharmaceuticals Inc; February 2021.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Other Special Considerations References	Q3 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions Quantity FDA-Approved Uses Compendial Approved Off-Labeled Uses References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Compendial Approved Off-Labeled Uses Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file