

5.01.50

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Anti-Infective Agents	Original Policy Date:	January 25, 2019
Subject:	Aemcolo	Page:	1 of 4

Last Review Date: March 12, 2021

Aemcolo

Description

Aemcolo (rifamycin)

Background

Aemcolo belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. Aemcolo is used for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E.coli*) in adults (1).

Regulatory Status

FDA-approved indication: Aemcolo is a rifamycin antibacterial indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults (1).

Limitations of Use:

Aemcolo is not indicated in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of *E. coli* (1).

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 (1).

The safety and effectiveness of Aemcolo in pediatric patients less than 18 years of age have not been established (1).

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Related policies

Viberzi, Xifaxan

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Aemcolo may be considered **medically necessary** for patients 18 years of age or older for the treatment of travelers' diarrhea and if the conditions indicated below are met.

Aemcolo is considered **investigational** in patients under 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Travelers' diarrhea caused by noninvasive strains of *Escherichia coli*
 - a. Patient does **NOT** have a fever > 38 degrees C (100.4 degrees F)
 - b. **NO** bloody stools or signs of systemic illness
 - c. **NO** dual therapy with another Prior Authorization (PA) medication for Travelers' diarrhea (see Appendix 1)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 18 years of age or older
Quantity 12 tablets per 365 days

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Prior - Approval Limits

Quantity	12 tablets per 90 days
Duration	3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Aemcolo belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase, blocking one of the steps in DNA transcription. Aemcolo is used for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* (*E.coli*) in adults. The safety and effectiveness of Aemcolo in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Aemcolo while maintaining optimal therapeutic outcomes.

References

1. Aemcolo [package insert]. Raleigh, NC: RedHill Biopharma, Inc.; December 2019.

Policy History

Date	Action
January 2019	Addition to PA
March 2019	Annual review. Added requirements of no fever > 38 degrees C, bloody stools, or signs of systemic illness per SME
December 2020	Annual review and reference update
March 2021	Annual review Updated fever temperature from 100 to 100.4 degrees F

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on

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March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of PA Travelers' Diarrhea Medications

Generic Name	Brand Name
rifamycin	Aemcolo
rifaximin	Xifaxan