

5.01.050

Section:	Prescription Drugs	Effective Date:	July 1, 2024
Subsection:	Anti-Infective Agents	Original Policy Date:	January 25, 2019
Subject:	Aemcolo	Page:	1 of 5

Last Review Date: June 13, 2024

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** if the conditions indicated below are met.

Aemcolo may be considered **investigational** 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

Prior - Approval Limits

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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.; February 2021.

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
March 2022	Annual review
September 2022	Annual review
March 2023	Annual review
March 2024	Annual review and reference update
June 2024	Annual review

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.

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Appendix 1 - List of PA Travelers' Diarrhea Medications

Generic Name	Brand Name
rifamycin	Aemcolo
rifaximin	Xifaxan