Clinical Policy: Rifamycin (Aemcolo)

Reference Number: ERX.NPA.113
Effective Date: 06.01.19
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Rifamycin (Aemcolo™) is an oral rifamycin antibacterial.

FDA Approved Indication(s)
Aemcolo is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults.

Limitation(s) of use: Aemcolo is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of *Escherichia coli*.

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

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Aemcolo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Travelers' Diarrhea (must meet all)**:**
1. Diagnosis of TD;
2. Age ≥ 18 years;
3. Failure of azithromycin 1,000 mg as a single dose, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 776 mg (4 tablets) per day.

Approval duration: 3 days

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Travelers' Diarrhea
1. May not be renewed as maximum allowed treatment duration is 3 days. Review initial approval criteria for new cases of travelers' diarrhea unrelated to original medication request.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 1 month (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TD: travelers' diarrhea

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azithromycin (Zithromax®)	1,000 mg PO single dose	500 mg/day PO is FDA-approved dosage; however, doses up to 1,200 mg/day PO are used off-label; 2 g PO when given as single dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): known hypersensitivity to rifamycin, any of the other rifamycin class antimicrobial agents (e.g., rifaximin), or any of the components in Aemcolo
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
TD	388 mg PO BID for 3 days	776 mg/day

VI. Product Availability
Delayed-release tablet: 194 mg

VII. References
1. Aemcolo Prescribing Information. San Diego, CA: Aries Pharmaceuticals, Inc.; November 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210910s000lbl.pdf. Accessed February 22, 2022.
2. Connor BA. Centers for Disease Control and Prevention: Travelers' diarrhea, chapter 2 – the pretravel consultation. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/travelers-diarrhea. Accessed February 17, 2021.
3. Riddle MS, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. J Travel Med. 2017:24(Suppl 1):S63-80.
4. DuPont HL, et al. Targeting of rifamycin SV to the colon for treatment of travelers' diarrhea: a randomized, double-blind, placebo-controlled phase 3 study. J Travel Med. 2014:21(6):369–76.
5. Steffen R, Jiang Z, Garcia MLG, et al., Rifamycin SV-MMX for treatment of travelers' diarrhea: equally effective as ciprofloxacin and not associated with the acquisition of multi-drug resistant bacteria. J Travel Med. Tay116, https://doi.org/10.1093/jtm/tay116. Published 20 November 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.23.19	05.19
2Q 2020 annual review: no significant changes; updated limitations of use; references reviewed and updated.	02.06.20	05.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	02.17.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.22.22	05.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.