

Clinical Policy: Rifamycin (Aemcolo)

Reference Number: PA.CP.PMN.196

Effective Date: 4.17.19

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[Revision Log](#)

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*.

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.

It is the policy of health plans affiliated with PA Health & Wellness® 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 \geq 18 years;
3. Failure of one of the following (a or b):
 - a. Fluoroquinolone regimens, unless contraindicated or clinically significant adverse effects are experienced (i, ii, or iii):
 - i. Ciprofloxacin 500 mg twice daily for 1-3 days;
 - ii. Levofloxacin 500 mg once daily for 1-3 days;
 - iii. Ofloxacin 200 mg twice daily for 1-3 days;
 - b. 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 per day (4 tablets per day).

Approval duration: 3 days

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 1 month (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – refer to PA.CP.PMN.53

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ciprofloxacin (Cipro [®])	500 mg PO BID for 1 to 3 days	1.5 g/day (regular release)
levofloxacin (Levaquin [®])	500 mg PO QD for 1 to 3 days	Usually 750 mg/day; occasionally higher dosages have been suggested
ofloxacin	200 mg PO BID for 1-3 days or 400 mg PO as a single dose or once daily for 3 days	800 mg/day
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	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 January 8, 2019.
2. Connor BA. Centers for Disease Control and Prevention: Travelers' diarrhea, chapter 2 – the pretravel consultation. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/travelers-diarrhea>. Accessed December 14, 2018.
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
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