

Clinical Policy Title:	rifamycin
Policy Number:	RxA.341
Drug(s) Applied:	Aemcolo™
Original Policy Date:	03/06/2020
Last Review Date:	9/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
rifamycin (Aemcolo™)	TD	388 mg orally twice daily	776 mg/day

Dosage Forms

- Delayed-release tablet: 194 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Travelers' Diarrhea (must meet all):

1. Diagnosis of Travelers' Diarrhea;
2. Age 18 years of age or older;
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 per day (4 tablets per day).

Approval duration

Commercial: 3 days

Medicaid: 3 days

II. Continued Therapy Approval

A. Travelers' Diarrhea

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy. May not be renewed as maximum allowed treatment duration is 3 days.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- Review initial approval criteria for new cases of travelers’ diarrhea unrelated to original request.
Approval duration: Not applicable

III. Appendices

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
azithromycin (Zithromax®)	1,000 mg oral administration single dose	500 mg/day oral administration is FDA-approved dosage; however, doses up to 1,200 mg/day oral administration are used off-label; 2 g oral administration 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

References

- 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.
- 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-pretravel-consultation/travelers-diarrhea>. Accessed December 14, 2018.
- 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.
- 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.
- 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 multidrug resistant bacteria. J Travel Med. Tay116, <https://doi.org/10.1093/jtm/tay116>. Published 20 November 2018.
- Aemcolo Prescribing Information. Raleigh, NC: RedHill Biopharma, Inc.; December, 2019. Available at: https://www.aemcolo.com/pdf/AEM19028_%20Aemcolo_PI_FINAL.pdf. Accessed June 18, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020

<p>Policy updated.</p> <ol style="list-style-type: none">1. Formatting updated.2. References updated.3. Clinical policy title updated.4. Drug(s) Applied updated.5. Lines of business updated.6. Continued therapy criteria updated.	<p>06/18/2020</p>	<p>09/14/2020</p>
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