Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2021**
Policy Number: PA.CP.PMN.196	**Effective Date: 04/2019** **Revision Date: 04/2021**
Policy Name: Rifamycin (Aemcolo)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Rifamycin (Aemcolo)

Reference Number: PA.CP.PMN.196
Effective Date: 4.17.19
Last Review Date: 04/2021

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.*

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.

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 ≥ 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 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
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 17, 2021.
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	04.17.19	
2Q 2020 annual review: requirement for a prior trial of a fluoroquinolone is removed due to concerns regarding increasing resistance to fluoroquinolones along with adverse dysbiotic (reduction in diversity of intestinal microbiota) and musculoskeletal adverse effects; references reviewed and updated.	04/2020	
2Q 2021 annual review: no significant changes; references reviewed and updated.	04/2021	