 <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC <b>Pharmacy Public Pharmacy Management Drug Policies</b>	<i>Policy Number</i>	MEDS094
		<i>Effective Date</i>	07/15/2015
		<i>Review Date</i>	01/12/2023
	<i>Subject</i> <b>Xifaxan and Aemcolo</b>	<i>Revision Date</i>	07/17/2019
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This document applies to the following Participating Organizations:

Priority Partners

**Keywords:** Xifaxan


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## **I. POLICY**

- A. Xifaxan (rifaximin) and Aemcolo (rifamycin) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20. Xifaxan will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate.
- PPMCO members are subject to the Priority Partners formulary, available at [www.ppmco.org](http://www.ppmco.org).
  - USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: [http://pec.ha.osd.mil/formulary\\_search.php?submenuheader=1](http://pec.ha.osd.mil/formulary_search.php?submenuheader=1)

## **II. POLICY CRITERIA**

- A. **Xifaxan** may be approved for the following:
- Hepatic encephalopathy** in patients, who meet all of the following:
    - Patient is 18 years of age or older
    - Documented diagnosis of hepatic encephalopathy
    - Documented trial and inadequate response to lactulose
  - Irritable Bowel Syndrome (IBS)** in patients, who meet all of the following:
    - Patient is 18 years of age or older
    - Documented diagnosis of diarrhea-predominant IBS
    - Documented trial and inadequate response to antispasmodic therapy (dicyclomine or hyoscyamine)
    - Documented trial and inadequate response to an additional formulary alternative
  - Traveler's Diarrhea** in patients, who meet all of the following:
    - Patient is 12 years of age or older
    - Documented diagnosis of traveler's diarrhea caused by non-invasive E.coli
    - Documented treatment failure or intolerance to a fluoroquinolone
      - If the patient is returning from an area of high fluoroquinolone resistance, an alternative trial and failure of azithromycin would be required

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4. The Request is for Xifaxan 200mg
- B. **Aemcolo** may be approved for the following:
  1. **Traveler's Diarrhea** in patients, who meet all of the following
  2. Patient is 18 years of age or older
  3. Documented diagnosis of traveler's diarrhea caused by non-invasive E.coli
  4. Documented treatment failure or intolerance to a fluoroquinolone
    1. If the patient is returning from an area of high fluoroquinolone resistance, an alternative trial and failure of azithromycin would be required

### **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. **Xifaxan:**
  1. Approval may be granted for the term of enrollment for Hepatic encephalopathy.
  2. Approval may be granted for 14 days of therapy for IBS-D. If a patient has documented recurrence of symptoms, re-approval can be authorized for up to two additional 14-day treatments.
  3. Approval may be granted for 3 days for traveler's diarrhea
- B. **Aemcolo:**
  1. Approval may be granted for 3 days for traveler's diarrhea

### **IV. EXCLUSIONS**

- A. Allergy to Xifaxan or Aemcolo or any of their components
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.


### **V. REFERENCES**

1. Xifaxan [prescribing information]. Raleigh, NC: Salix Pharmaceuticals, Inc.; 2022 September
2. Aemcolo [prescribing information]. San Diego, CA; Aries Pharmaceuticals Inc.; 2019 December
3. Ford AC, Moayyedi P, Lacy BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. Am J Gastroenterol 2014; 109
4. Bajaj JS. Review article: the modern management of hepatic encephalopathy. Aliment Pharmacol Ther 2010; 31:537.

### **VI. APPROVALS**

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/20/2016	Updated criteria for the covered indications; included strep criteria and patient specific qualifiers; Clarified authorization periods; Updated references
07/27/2017	Updated Exclusions section regarding physician samples

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05/02/2019	Clarified authorization duration for the IBS-D indication based on the FDA-approved prescribing information
07/17/2019	Updated criteria for Traveler's diarrhea based on the clinical guidelines considering the emergence of fluoroquinolone resistance; add clinical criteria for Aemcolo

Review Dates: 07/15/2015, 7/20/2016, 07/17/2019, 01/12/2023

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