SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Gastrointestinal (GI) Oral PDL Edit
First Implementation Date:	October 5, 2017
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: A variety of antibiotics are utilized in the treatment of gastrointestinal related infections and bacterial vaginosis. The most common symptom of gastrointestinal (GI) infections is diarrhea, which may be mild to severe. Traveler's diarrhea, amebiasis, giardiasis, cryptosporidiosis, and trichomoniasis are all GI conditions that are amenable to treatment with the GI antibiotics. Another condition for which these agents are used is hepatic encephalopathy (HE) which may occur in cases with cirrhosis and is characterized by altered consciousness, behavior, and motor function due primarily to the accumulation of ammonia in the blood. Second-line therapy can include rifaximin and is intended to reduce nitrogen load from the GI tract and improve CNS status. *Clostridioides difficile* (*C. difficile*)-associated diarrhea can be an unavoidable consequence of prior antimicrobial use. The bacterium multiplies in the colon and produces toxins that stimulate a process in the colon leading to colitis, which is characterized by watery, and occasionally, bloody diarrhea. A 2021 Focused Update to the clinical practice guideline for adults by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) recommends fidaxomicin over vancomycin in patients with an initial *C. difficile* infection (severe or non-severe) or first recurrence. However, the guideline maintains that vancomycin is an acceptable alternative in both instances. The most current recommendations for pediatrics reference the 2017 IDSA guidelines which suggest either metronidazole or vancomycin for non-severe, initial or first recurrence episodes. Fidaxomicin is a macrolide antibiotic indicated for the treatment of diarrhea due to *C. difficile*. Metronidazole is commonly utilized for bacterial vaginosis but is also indicated for pelvic inflammatory disease, serious anaerobic infections, in addition to treatment of infections of the GI tract. Neomycin is used as a bowel preparation prior to colorectal surgery as well as an adjunctive agent for the treatment of HE or hepatic coma. Xifaxan® is indicated for treatment of traveler's diarrhea due to noninvasive strains of *Escherichia coli* in adults and pediatric patients aged 12 or older as well as for the reduction in risk of overt HE recurrence and treatment of irritable bowel syndrome with diarrhea in adults.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Metronidazole Tabs • Neomycin • Vancomycin Caps	• Aemcolo® • Alinia® • Dificid® • Firvanq® • Flagyl® • Metronidazole Caps • Nitazoxanide • Paromomycin • Tinidazole • Vancocin® • Vancomycin Soln • Xifaxan®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Antibiotics, Gastrointestinal (GI), Oral Agents
- Age range: All appropriate MO HealthNet participants aged 6 months or older

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **OR**
- **For fidaxomicin**:
  - Documented diagnosis of diarrhea due to Clostridium difficile in the past 30 days **AND**
  - Participant aged 6 months or older **AND**
  - For participants aged 6 months to 17 years: adequate therapeutic trial of metronidazole **OR** vancomycin in the past 30 days **OR**
  - For participants aged 18 years or older: adequate therapeutic trial of vancomycin in the past 30 days
- **For nitazoxanide**:
  - Documented diagnosis of diarrhea caused by Giardia lambia or Cryptosporidium parvum in the past 30 days **AND**
  - Participant aged 1 year or older
- **For paromomycin**:
  - Documented diagnosis of intestinal amebiasis OR hepatic coma in the past 30 days **AND**
  - Participant aged 1 year or older
- **For rifaximin 200 mg tablets**:
  - For a documented diagnosis of travelers' diarrhea in the past 30 days:
    - Participant aged 12 years or older **AND**
    - Adequate therapeutic trial of a fluoroquinolone OR azithromycin in the past 30 days **AND**
    - Dosed at 200 mg three times daily for a duration of ≤3 days **AND**
    - Limit of 1 claim in past 30 days
- **For rifaximin 550 mg tablets**:
  - For a documented diagnosis of hepatic encephalopathy in the past 2 years:
    - Participant aged 18 years or older **AND**
    - Adequate therapeutic trial of lactulose OR neomycin in the past year **AND**
    - Dosed at 550 mg two times daily

    - For a documented diagnosis of irritable bowel syndrome with diarrhea in the past year:
        - Participant aged 18 years or older **AND**
        - Adequate therapeutic trial of 1 or more anti-diarrheal agents in the past 45 days **AND**
        - Dosed at 550 mg three times daily for a duration of ≤ 14 days
    - For a documented diagnosis of small intestinal bacterial overgrowth (SIBO) in the past year:
        - Participant aged 18 years or older **AND**
        - Adequate therapeutic trial of ciprofloxacin OR metronidazole in the past 30 days **AND**
        - Dosed at 550 three times daily for a duration of ≤ 14 days
- **For rifamycin:**
    - **Documented diagnosis of travelers' diarrhea in the past 30 days AND**
    - **Age ≥ 18 years**
    - **Adequate therapeutic trial of a fluoroquinolone OR azithromycin in the past 30 days AND**
    - **Dosed at 388 mg two times daily for a duration of ≤ 3 days AND**
    - **Limit of 1 claim in past 30 days**
- **For tinidazole**:
    - Documented diagnosis of intestinal amebiasis, amebic liver abscess, bacterial vaginosis, giardiasis, OR trichomoniasis in the past 30 days
    - Participant aged 3 years or older **AND**
    - Adequate therapeutic trial of metronidazole in the past 30 days

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Gastrointestinal Antibiotics – Oral", UMKC-DIC; March 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Gastrointestinal Antibiotics – Oral – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- McDonald LC, Gerding DN, Johnson S, et.al. Clinical practice guidelines for clostridium difficile infection in adults and children: 2017 update by the infectious diseases society of America (IDAS) and Society of Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7). Infectious Diseases Society of America. https://www.idsociety.org/practice-guideline/clostridium-difficile/.
- Johnson, S., Lavergne, V., et.al. Clinical Practice Guideline by the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults. Clinical Infectious Diseases, 2021;, ciab549, https://doi.org/10.1093/cid/ciab549.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.