SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Gastrointestinal (GI) Oral PDL Edit
First Implementation Date:	October 5, 2017
Proposed Date:	June 17, 2021
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 treated by these agents is hepatic encephalopathy which occurs in 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. Clostridium 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. An updated 2017 clinical practice guideline by the Infectious Diseases Society of America and Society for Healthcare Epidemiology of America recommends oral metronidazole for an initial episode of mild to moderate (non-severe) C. difficile infection if access to vancomycin or fidaxomicin is limited; oral vancomycin or oral fidaxomicin is recommended for an initial episode of severe C. difficile infection. Fidaxomicin is a macrolide antibiotic indicated for the treatment of diarrhea due to C. difficile. Metronidazole is most 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 hepatic encephalopathy or hepatic coma. Xifaxan has the sole indication of treatment of traveler's diarrhea due to noninvasive strains of *Escherichia coli.*

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Metronidazole Tabs • Neomycin • Vancomycin Caps	• 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: approved as first-line therapy with a documented diagnosis of diarrhea due to Clostridium difficile in the past 30 days:
  - Participant aged 6 months or older **AND**
  - Adequate therapeutic trial of metronidazole OR vancomycin in the past 30 days **OR**
- For nitazoxanide:
  - Participant aged 1 year or older **AND**
  - Documented diagnosis of diarrhea due to Giardia lambia or Cryptosporidium parvum **OR**
- For paromomycin: approved as first-line therapy with a documented diagnosis of intestinal amebiasis OR hepatic coma in the past 30 days:
  - Participant aged 1 year or older **OR**
- For tinidazole: approved as first-line therapy with a 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 **OR**
- For rifaximin 550mg tablets: approved as first-line therapy with 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 550mg two times daily **OR**
- For rifaximin 550mg tablets: approved as first-line therapy with 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 550mg three times daily for a duration of ≤14 days **OR**
- For rifaximin 200mg tablets: approved as first-line therapy with a documented diagnosis of traveler's 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 200mg three times daily for a duration of ≤3 days **AND**
    - Limit of 1 claim in past 30 days **OR**
- For rifaximin 200mg tablets: approved as first-line therapy with 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 200mg six times daily for a duration of ≤7 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

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5. Xifaxan [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; October 2020.
6. Tindamax [package insert]. San Antonio, TX: Mission Pharmacal Company; September 2020.
7. Neomycin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; March 2020.
8. Firvanq [package insert]. Wilmington, MA: Azurity Pharmaceuticals; December 2020.
9. Vancocin [package insert]. Baudette, MN: Ani Pharmaceuticals; 2018
10. Dificid [package insert]. Whitehouse Station, NJ; Merck Sharp & Dohme Corp; December 2020.
11. Flagyl [package insert]. New York, NY: G.D. Searle LLC; March 2021.
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13. 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/