



SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Gastrointestinal (GI), Oral Agents PDL Edit
First Implementation Date:	October 5, 2017
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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-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 American and Society for Healthcare Epidemiology of America recommends oral metronidazole for an initial episode of mild to moderate (non-severe) C. difficile infection; oral vancomycin or oral fidaxomicin is recommended over oral metronidazole for an initial episode of severe C. difficile infection. Fidaxomicin is a newer macrolide antibiotic indicated for the treatment of diarrhea due to Clostridium difficile. Metronidazole is indicated most commonly for bacterial vaginosis but can still treat GI infections. Neomycin is used as a bowel preparation prior to GI surgery.

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

- 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 no approval criteria are met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

Default Approval Period

1 year

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Evidence-Based Medicine and Fiscal Analysis: “Gastrointestinal Antibiotics – Oral – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; May 2020.
5. Evidence-Based Medicine Analysis: “Gastrointestinal Antibiotics – Oral”, UMKC-DIC; April 2020.
6. Xifaxan [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; 2018.
7. Tindamax [package insert]. San Antonio, TX: Mission Pharmacal Company; 2019.
8. Neomycin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; 2018.
9. Firvanq [package insert]. Wilmington, MA: CutisPharma; 2019.
10. Vancocin [package insert]. Baudette, MN: Ani Pharmaceuticals; 2018
11. Difidic [package insert]. Whitehouse Station, NJ; Merck Sharp & Dohme Corp; 2020.
12. Flagyl [package insert]. New York, NY: G.D. Searle LLC; 2018.
13. Flagyl capsules [package insert]. New York, NY: G.D. Searle LLC; 2018.
14. 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/>

SmartPA PDL Proposal Form

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