SmartPA Criteria Proposal

<table>
<thead>
<tr>
<th>Drug/Drug Class:</th>
<th>Antibiotics, Gastrointestinal (GI), Oral Agents PDL Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Implementation Date:</td>
<td>October 5, 2017</td>
</tr>
<tr>
<td>Revised Date:</td>
<td>October 1, 2020</td>
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<tr>
<td>Prepared For:</td>
<td>MO HealthNet</td>
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<td>Prepared By:</td>
<td>MO HealthNet/Conduent</td>
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<tr>
<td>Criteria Status:</td>
<td>☒ Revision of Existing Criteria ☐ New Criteria</td>
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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.
### Program-Specific Information:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
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<tbody>
<tr>
<td>• Metronidazole Tabs</td>
<td>• Alinia®</td>
</tr>
<tr>
<td>• Neomycin</td>
<td>• Dificid®</td>
</tr>
<tr>
<td>• Vancomycin Caps</td>
<td>• Firvanq™</td>
</tr>
<tr>
<td></td>
<td>• Flagyl®</td>
</tr>
<tr>
<td></td>
<td>• Metronidazole Caps</td>
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<tr>
<td></td>
<td>• Paromomycin</td>
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<tr>
<td></td>
<td>• Tinidazole</td>
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<tr>
<td></td>
<td>• Vancocin®</td>
</tr>
<tr>
<td></td>
<td>• Vancomycin Soln</td>
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<tr>
<td></td>
<td>• Xifaxan®</td>
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### 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 2 or more covered 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:
  o Participant aged 12 years or older AND
  o Adequate therapeutic trial of a fluoroquinolone OR azithromycin in the past 30 days AND
  o Dosed at 200mg three times daily for a duration of ≤3 days AND
  o 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:
  o Participant aged 18 years or older AND
  o Adequate therapeutic trial of ciprofloxacin OR metronidazole in the past 30 days AND
  o 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: ☐  Progress Notes: ☐
MedWatch Form: ☐  Other: ☐

Disposition of Edit

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

Default Approval Period

1 year

References

2. USPDI, Micromedx; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.