Executive Summary

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

**Why Issue Selected:** Intravaginal antibiotics are indicated for vaginal infections. All the intravaginal antibiotics included on the intravaginal antibiotics PDL list are FDA approved for the treatment of Bacterial Vaginosis (BV). BV is a condition caused by a shift in vaginal microbiota away from the *Lactobacillus* species toward more diverse bacterial species. The change in bacteria causes the pH in the vagina to increase, and participants’ symptoms can range from none to intolerable. Treatment is indicated for symptom relief in females with symptomatic BV and as prevention of a postoperative infection for those who are asymptomatic. Treatment of BV with the use of these agents may decrease the risk of getting sexually transmitted diseases such as HIV. It is recommended to still treat asymptomatic participants who are not pregnant. Contraindications, warnings, adverse drug events, and drug interactions are similar for all products used for the treatment of BV are considered class effects.

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

<table>
<thead>
<tr>
<th>Program-Specific Information:</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Cleocin® Vaginal Ovules</td>
<td>• Cleocin® Vaginal Crm</td>
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<tr>
<td></td>
<td>• Clindesse®</td>
<td>• Clindamycin Vaginal Crm</td>
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<td></td>
<td>• Nuvessa™ Vaginal Gel</td>
<td>• MetroGel Vaginal® Gel</td>
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<td></td>
<td>• Vandazole® Vaginal Gel</td>
<td>• Metronidazole Vaginal Gel</td>
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<td>• Solosec™</td>
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</table>

**Type of Criteria:**
- ☒ Increased risk of ADE
- ☒ Preferred Drug List
- ☐ Appropriate Indications
- ☒ Clinical Edit
- ☐ Only Administrative Databases
- ☒ Databases + Prescriber-Supplied

**Setting & Population:**
- Drug class for review: Antibiotics, Vaginal Agents
- Age range: All appropriate MO HealthNet participants
Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents OR 1 preferred agent AND oral metronidazole
  - Documented trial period of preferred agents OR
  - Documented ADE/ADR to preferred agents AND
- For Solosec:
  - Participant aged 18 years or older AND
  - Documented diagnosis of bacterial vaginosis in the past 30 days

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
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<tbody>
<tr>
<td>MedWatch Form:</td>
<td>Other:</td>
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</table>

Disposition of Edit

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

Default Approval Period

1 year

References

4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.