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 developing sexually transmitted diseases such as HIV. This concept has led to the use of these antibiotic agents in BV-infected individuals regardless of the presence or absence of symptoms. However, consensus recommendations dictate it is not necessary to treat asymptomatic patients unless they are pregnant. Contraindications, warnings, adverse drug events, and drug interactions are similar for all products used for the treatment of BV and are considered a class effect.

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>
</tr>
</thead>
<tbody>
<tr>
<td>Cleocin® Vaginal Ovules</td>
<td>Cleocin® Vaginal Crm</td>
</tr>
<tr>
<td>Clindesse®</td>
<td>Clindamycin Vaginal Crm</td>
</tr>
<tr>
<td>Nuvessa™ Vaginal Gel</td>
<td>MetroGel Vaginal® Gel</td>
</tr>
<tr>
<td>Vandazole® Vaginal Gel</td>
<td>Metronidazole Vaginal Gel</td>
</tr>
<tr>
<td>Solosec®</td>
<td></td>
</tr>
</tbody>
</table>

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

Data Sources: ☒ Databases + Prescriber-Supplied
☐ Only Administrative Databases
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 in the past 3 months
  - Documented trial period of preferred agents OR
  - Documented ADE/ADR to preferred agents OR
- For Solosec: participant aged 18 years or older AND
  - Documented diagnosis of trichomoniasis AND
  - Adequate therapeutic trial of oral metronidazole in the past 3 months
  - 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 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

3 months

References

3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.