

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antibiotics, Vaginal PDL Edit
<b>First Implementation Date:</b>	June 16, 2009
<b>Revised Date:</b>	October 14, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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:** 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:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Cleocin® Vaginal Ovules</li> <li>• Clindesse®</li> <li>• Nuversa™ Vaginal Gel</li> <li>• Vandazole® Vaginal Gel</li> </ul>	<ul style="list-style-type: none"> <li>• Cleocin® Vaginal Crm</li> <li>• Clindamycin Vaginal Crm</li> <li>• MetroGel Vaginal® Gel</li> <li>• Metronidazole Vaginal Gel</li> <li>• Solosec®</li> </ul>

**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, 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:  
MedWatch Form:

  

Progress Notes:  
Other:

  

## Disposition of Edit

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

## Default Approval Period

**3 months**

## References

1. Evidence-Based Medicine Analysis: "Intravaginal Antibiotics", UMKC-DIC; March 2021.
2. Evidence-Based Medicine and Fiscal Analysis: "Vaginal Antibiotics – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
5. Cleocin Vaginal Ovules [package insert]. New York, NY: Pharmacia & Upjohn; March 2020.
6. Cleocin Vaginal Cream [package insert]. New York, NY: Pharmacia & Upjohn; March 2020.
7. Clindesse [package insert]. Allegan, MI: Perrigo; 2018.
8. Nuversa Vaginal Gel [package insert]. Florham Park, NJ: Exeltis USA, Inc.; August 2018.
9. Vandazole Vaginal Gel [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2021.
10. Sobel, J., & Mitchell, C., (2020). Bacterial vaginosis: clinical manifestations and diagnosis. In K. Eckler (Ed.), UpToDate.

*SmartPA PDL Proposal Form*

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11. Sobel, J., Bacterial vaginosis: Treatment. 26 March 2021. [www.uptodate.com](http://www.uptodate.com).
12. Solosec [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; June 2021.