

SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Vaginal Agents PDL Edit
First Implementation Date:	June 16, 2009
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: 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.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> Cleocin® Vaginal Ovules Clindesse® Nuessa™ Vaginal Gel Vandazole® Vaginal Gel 	<ul style="list-style-type: none"> Cleocin® Vaginal Crm Clindamycin Vaginal Crm MetroGel Vaginal® Gel Metronidazole Vaginal Gel Solosec™

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

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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

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. Evidence-Based Medicine Analysis: "Intravaginal Antibiotics", UMKC-DIC; March 2020.
2. Evidence-Based Medicine and Fiscal Analysis: "Vaginal Antibiotics – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
6. Cleocin Vaginal Ovules [package insert]. New York, NY: Pharmacia & Upjohn; 2020.
7. Cleocin Vaginal Cream [package insert]. New York, NY: Pharmacia & Upjohn; 2020.
8. Clindesse [package insert]. Allegan, MI: Perrigo; 2018.
9. MetroGel-Vaginal Gel [package insert]. Scottsdale, AZ: Medicis Pharmaceutical Corp; 2014.
10. Nuversa Vaginal Gel [package insert]. Florham Park, NJ: Exeltis USA, Inc; 2018.
11. Vandazole Vaginal Gel [package insert]. Maple Grove, MN: Upsher-Smith; 2017.
12. Sobel, J., & Mitchell, C., (2020). Bacterial vaginosis: clinical manifestations and diagnosis. In K. Eckler (Ed.), *UpToDate*.
13. Sobel, J., (2020). Bacterial vaginosis: treatment. In K. Eckler (Ed.), *UpToDate*.

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