

SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Vaginal PDL Edit
First Implementation Date:	June 16, 2009
Proposed Date:	September 15, 2022
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 within this class 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, anaerobic, bacterial species leading to a resultant increase in vaginal pH. Treatment is indicated for symptomatic females and as prevention of postoperative infections 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.

Within the class, Solosec® (secnidazole) is the only product with an additional indication. In July 2021, it was approved for the treatment of trichomoniasis, a sexually transmitted disease caused *Trichomonas vaginalis* (*T. vaginalis*), a protozoan parasite. Approximately only 30% of infected individuals are symptomatic. Solosec is a nitroimidazole antimicrobial, the only class known to be effective against *T. vaginalis* infections. Other products within this class utilized for treatment of trichomoniasis include metronidazole and tinidazole. Reinfection of trichomoniasis occurs in approximately 1 out of 5 individuals within three months of treatment. Subsequent treatment regimens are determined based on prior courses of therapy, source of reexposure, or persistent infections not attributable to reexposure.

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® Metronidazole Vaginal Gel Nuversa® Vaginal Gel Vandazole® Vaginal Gel 	<ul style="list-style-type: none"> Cleocin® Vaginal Crm Clindamycin Vaginal Crm Solosec®

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 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 treatment of trichomoniasis:**
 - **Claim is for Solosec AND**
 - **Participant aged 12 years or older AND**
 - **Documented diagnosis of trichomoniasis AND**
 - **Adequate therapeutic trial of oral metronidazole in the past 3 months**

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

- Evidence-Based Medicine Analysis: "Intravaginal Antibiotics", UMKC-DIC; June 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Vaginal Antibiotics – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- Sobel, J., & Mitchell, C., (2020). Bacterial vaginosis: clinical manifestations and diagnosis. In K. Eckler (Ed.), UpToDate.
- Sobel, J., Bacterial vaginosis: Treatment. 26 March 2021. www.uptodate.com.

SmartPA PDL Proposal Form

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- Centers for Disease Control and Prevention (CDC): Sexually Transmitted Infections Treatment Guidelines, 2021. <https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf>.
- Solosec [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; January 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.

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