

Clinical Policy Title:	secnidazole
Policy Number:	RxA.481
Drug(s) Applied:	Solosec®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Secnidazole (Solosec®) is a 5-nitroimidazole antimicrobial. It is indicated for the treatment of bacterial vaginosis (BV) in adult women.

Limitation(s) of use: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Solosec® and other antibacterial drugs, Solosec® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
secnidazole (Solosec®)	Bacterial vaginosis	2 g PO as a single-dose	2 g as a single-dose

Dosage Forms

- Oral granules: 2 g

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Bacterial Vaginosis (must meet all):

1. Diagnosis of bacterial vaginosis (BV);
2. Age 18 years or more;
3. Failure of both of the following agents (*see Appendix B*): metronidazole and clindamycin, with at least one of the agents used within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed a single-dose of 2 grams (1 packet).

Approval duration

Commercial: 7 days (1 packet total)

Medicaid: 7 days (1 packet total)

II. Continued Therapy Approval

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

A. Bacterial Vaginosis (must meet all):

1. Re-authorization is not permitted. Members must meet the initial approval criteria and at least 14 days should have elapsed since the previous claim for Solosec®.

Approval Duration

Commercial: Not applicable

Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

CDC: Centers for Disease Control

FDA: Food and Drug Administration

BV: Bacterial Vaginosis

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
clindamycin (Clindesse® vaginal cream, Cleocin®)	Intravaginal 2% cream: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally at bedtime for 7 days* <ul style="list-style-type: none"> • The FDA-approved regimen for most products is 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally at bedtime for 3 or 7 consecutive days in non-pregnant patients and for 7 days in pregnant patients. The dose for Clindesse vaginal cream is 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally as a single dose at any time of the day. • Intravaginal ovules/suppositories: 1 ovule (100 mg clindamycin) inserted intravaginally at bedtime for 3 days** Oral [†] : 300 mg PO BID for 7 days**	See dosing regimen

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
metronidazole (Flagyl®, MetroGel- Vaginal®, Nuversa®, Vandazole®)	<p>0.75% vaginal gel (MetroGel-vaginal): 1 applicatorful (5 g of 0.75% metronidazole gel) intravaginally 1 to 2 times daily for 5 days</p> <p>0.75% vaginal gel (Vandazole): One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily for 5 days*</p> <p>1.3% vaginal gel: One applicator (5 g of 1.3% gel containing 65 mg of metronidazole) administered intravaginally as a single dose at bedtime. Only approved for use in non-pregnant women.</p> <p>Regular-release tablet[†]: 500 mg PO BID for 7 days*</p>	See dosing regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

[†]Off-label indication

*Recommended regimen per CDC

**Alternative regimen per CDC

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - History of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives
- Boxed Warning(s):
 - None reported

APPENDIX D: General Information

- Prescribing Solosec® in the absence of proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
- **CDC Treatment Regimens for Bacterial Vaginosis**
 - Metronidazole 500 mg orally twice a day for 7 days
 - Metronidazole gel 0.75%, one full applicator (5 g) intravaginally, once a day for 5 days
 - Clindamycin cream 2%, one full applicator (5 g) intravaginally at bedtime for 7 days
 - Clindamycin 300 mg orally twice daily for 7 days
 - Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days
 - Tinidazole 2 g orally once daily for 2 days, or 1 g orally once daily for 5 days

References

1. Solosec® Prescribing Information. Baltimore, MD: Lupin Pharmaceuticals, Inc.; October 2019. Available at: <https://www.solosec.com/>. Accessed September 14, 2020.
2. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines: Bacterial Vaginosis. June 2015. Available at: <https://www.cdc.gov/std/tg2015/bv.htm>. Accessed September 14, 2020.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: <http://www.clinicalkey.com>. Updated January 14, 2020. Accessed September 14, 2020.
4. Secnidazole, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed September 14, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Solosec was replaced with “Solosec®” throughout policy for consistency. 3. Appendix A: BV was added. 4. Appendix B: Pre table phrase was updated to “<i>Below are suggested therapeutic alternatives..</i>” 5. References were updated. 	9/14/2020	12/07/2020