Clinical Policy: Secnidazole (Solosec)

Reference Number: PA.CP.PMN.103
Effective Date: 10.24.17
Last Review Date: 01.19 Revision Log

Description
Secnidazole (Solosec™) is a 5-nitroimidazole antimicrobial.

FDA Approved Indication(s)
Solosec is indicated for the treatment of bacterial vaginosis 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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness that Solosec is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Bacterial Vaginosis (must meet all)**:**

1. Diagnosis of bacterial vaginosis;
2. Age ≥ 18 years;
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: 7 days (1 packet total)

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Bacterial Vaginosis (must meet all)**:**

1. Members must meet the initial approval criteria and at least 14 days should have elapsed since the previous claim for Solosec.

Approval duration: Not Applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 7 days (whichever is less); or

2. Refer to PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CDC: Centers for Disease Control
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

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* • 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
metronidazole (Flagyl®, MetroGel-Vaginal®, Nuvessa®, Vandazole®)	0.75% vaginal gel (MetroGel-vaginal): 1 applicatorful (5 g of 0.75% metronidazole gel) intravaginally 1 to 2 times daily for 5 days 0.75% vaginal gel (Vandazole): One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily for 5 days*	See dosing regimen

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
	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. Regular-release tablet†: 500 mg PO BID for 7 days*	

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: 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Bacterial vaginosis	2 g PO as a single-dose	2 g as a single-dose

VI. Product Availability

Oral granules: 2 g

VII. References

1. Solosec Prescribing Information. Baltimore, MD: Lupin Pharmaceuticals, Inc.; October 2017. Available at: https://www.solosec.com/. Accessed September 24, 2018.
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 24, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed September 24, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: references reviewed and updated.	01/19	