# Clinical Policy: Secnidazole (Solosec)

Reference Number: ERX.NPA.55
Effective Date: 03.01.18
Last Review Date: 02.22 Revision Log
Line of Business: Commercial, Medicaid

**See Important Reminder at the end of this policy for important regulatory and legal information.**

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

**FDA Approved Indication(s)**
Solosec is indicated for the treatment of:
- Bacterial vaginosis in female patients 12 years of age and older
- Trichomoniasis in patients 12 years of age and older

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

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 12 years;
3. Failure of two of the following agents, with at least one of the agents used within the last 6 months, unless clinically significant adverse effects are experienced or all are contraindicated: metronidazole, clindamycin, tinidazole (*see Appendix B and D for regimens*);
4. Dose does not exceed a single dose of 2 grams (1 packet).

**Approval duration: 7 days (1 packet total)**

**B. Trichomoniasis** (must meet all)**:**
1. Diagnosis of trichomoniasis;
2. Age ≥ 12 years;
3. Failure of metronidazole and tinidazole*, unless both are contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required.*
4. Dose does not exceed a single dose of 2 grams (1 packet).

**Approval duration: 7 days (1 packet total)**

**C. Other diagnoses/indications**
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Bacterial Vaginosis**

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: Not applicable**

**B. Trichomoniasis**

1. Re-authorization is not permitted. Members must meet the initial approval criteria and at least 12 days should have elapsed since the previous claim for Solosec.

**Approval duration: Not applicable**

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 7 days (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## 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 – ERX.PA.01 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*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Bacterial vaginosis** | | |
| clindamycin (Clindesse® vaginal cream, Cleocin®) | Intravaginal 2% cream in adults: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally at bedtime for 7 days*<br>• 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.<br><br>Intravaginal 2% cream in post-menarchal adolescents†: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally as a single dose<br><br>Intravaginal ovules/suppositories in adults and post-menarchal adolescents: 1 ovule (100 mg clindamycin) inserted intravaginally at bedtime for 3 days**<br><br>Oral in adults† and adolescents†: 300 mg PO BID for 7 days** | See dosing regimen |
| metronidazole (Flagyl®, MetroGel- | 0.75% vaginal gel (MetroGel-vaginal): 1 applicatorful (5 g of 0.75% metronidazole gel) intravaginally 1 to 2 times daily for 5 days in adults; | See dosing regimen |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Vaginal®, Nuvessa®, Vandazole®) | One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily for 5 days in post-menarchal adolescents†<br><br>0.75% vaginal gel (Vandazole): One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily for 5 days in adults* and post-menarchal adolescents†<br><br>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 in adult women, and adolescents 12-17 years†<br><br>Regular-release tablet†: 500 mg PO BID for 7 days* for adults, children > 45 kg and adolescents; 15 to 25 mg/kg/day PO TID for 7 days in children weighing < 45 kg | |
| tinidazole (Tindamax®) | Adults and adolescents†: 2 g PO QD for 2 days or 1 g PO QD for 5 days** | See dosing regimen |
| **Trichomoniasis** | | |
| metronidazole (Flagyl®) | Children weighing < 45 kg†: 45 mg/kg/day PO TID for 7 days<br>Female children weighing ≥ 45 kg and adolescents†: 500 mg PO BID for 7 days.<br>Male children weighing ≥ 45 kg and adolescents†: A single 2-g dose PO<br>Adults: A single 2-g dose PO* or 500 mg PO BID for 7 days* | See dosing regimen |
| tinidazole (Tindamax®) | Adults and adolescents†: A single 2-g dose PO** | 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 in adults*
***Alternative regimen per CDC in adults*

*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
- Solosec 2 g oral granules in a single dose

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Bacterial vaginosis, trichomoniasis | 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.; January 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209363Orig1s014s016lbl.pdf. Accessed February 14, 2022.
2. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines: Trichomoniasis. 2021. Available at: https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm. Accessed October 15, 2021.
3. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines: Bacterial Vaginosis. 2021. Available at: https://www.cdc.gov/std/treatment-guidelines/bv.htm. Accessed October 15, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed February 14, 2022.
5. Paladine, H, Desai U. Vaginitis: diagnosis and treatment. March 2018. Am Fam Physician. 2018;97(5):321-329.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 10.24.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 09.24.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; added maximum dose in section V; references reviewed and updated. | 10.28.19 | 02.20 |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 11.04.20 | 02.21 |
| RT4: Criteria added new indication and its criteria for initial and continued therapy; references reviewed and updated. | 07.21.21 | 11.21 |
| 1Q 2022 annual review: no significant changes; updated Appendix D; RT4: updated Solosec indications for pediatric extension to age ≥ 12 years; references reviewed and updated. | 10.15.21 | 02.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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