Clinical Policy: Secnidazole (Solosec)

Reference Number: CP.PMN.103
Effective Date: 03.01.18
Last Review Date: 02.23
Line of Business: Commercial, HIM, Medicaid Revision Log

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.

It is the policy of health plans affiliated with Centene Corporation® 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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
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 * • 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 2% cream in post-menarchal adolescents†: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally as a single dose Intravaginal ovules/suppositories in adults and post-menarchal adolescents: 1 ovule (100 mg clindamycin) inserted intravaginally at bedtime for 3 days** 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† 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† 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† 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 1g PO QD for 5 days**	See dosing regimen
Trichomoniasis		
metronidazole (Flagyl®)	Children weighing < 45 kg†: 45 mg/kg/day PO TID for 7 days Female children weighing ≥ 45 kg and adolescents†: 500 mg PO BID for 7 days. Male children weighing ≥ 45 kg and adolescents†: A single 2-g dose PO 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, or other nitroimidazole derivatives; patients with Cockayne syndrome
- 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 November 15, 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 November 15, 2022.
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 November 15, 2022.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed November 15, 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 change from previously approved policy; references reviewed and updated.	09.24.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.28.19	02.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; 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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; for bacterial vaginosis, added tinidazole as an option to try/fail; updated Appendix D; RT4: updated Solosec indications for pediatric extension to age ≥ 12 years; references reviewed and updated.	10.15.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.15.22	02.23

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.