Clinical Policy: Secnidazole (Solosec)

Reference Number: CP.PMN.103
Effective Date: 10.24.17
Last Review Date: 02.18 Revision Log
Line of Business: Commercial, Health Insurance Marketplace, 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 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 (including 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 ≥ 18 years;
3. Failure of both of the following agents (*see Appendix B for regimens*): 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

Each request should be evaluated against the initial approval criteria and at least 14 days should have elapsed since the previous claim for Solosec.

Approval duration: N/A

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 7 days (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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
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**	See dosing regimen

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
	Oral†: 300 mg PO BID for 7 days**	
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* 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*	See dosing regimen
tinidazole (Tindamax®)	2 g PO QD for 2 days or 1 g PO QD for 5 days**	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: 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. Newark NJ: Symbiomix Therapuetics. September 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209363s000lbl.pdf. Accessed September 18, 2017.
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 11, 2017.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed October 9, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.24.17	02.18

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.