

**Clinical Policy: Secnidazole (Solosec)**

Reference Number: CP.PMN.103

Effective Date: 03.01.18

Last Review Date: 02.21

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 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 (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*): metronidazole and clindamycin, with at least one of the agents used within the last 6 months, unless both are 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.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy****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: Not applicable**

**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.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
clindamycin (Clindesse <sup>®</sup> vaginal cream, Cleocin <sup>®</sup> )	<p>Intravaginal 2% cream: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally at bedtime for 7 days*</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>Intravaginal ovules/suppositories: 1 ovule (100 mg clindamycin) inserted intravaginally at bedtime for 3 days**</p>	See dosing regimen

Drug Name	Dosing Regimen*	Dose Limit/ Maximum Dose
	Oral <sup>†</sup> : 300 mg PO BID for 7 days**	
metronidazole (Flagyl <sup>®</sup> , MetroGel- Vaginal <sup>®</sup> , Nuversa <sup>®</sup> , Vandazole <sup>®</sup> )	<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<sup>†</sup>: 500 mg PO BID for 7 days*</p>	See dosing regimen

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

<sup>†</sup>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 2019. Available at: <https://dailymed.nlm.nih.gov>. Accessed November 4, 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 November 4, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed November 4, 2020.
4. 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

## **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.

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**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.

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