Clinical Policy: Secnidazole (Solosec)
Reference Number: ERX.NPA.55
Effective Date: 10.24.17
Last Review Date: 02.19

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.

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 ≥ 18 years;
      3. Failure of two of the following agents (see Appendix B and D for regimens): metronidazole, clindamycin, or tinidazole, 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 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. 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).

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

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
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<tbody>
<tr>
<td>clindamycin (Clindesse® vaginal cream, Cleocin®)</td>
<td>Intravaginal 2% cream: 1 applicatorful (100 mg clindamycin/5 g cream) intravaginally at bedtime for 7 days*&lt;br&gt;• 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.&lt;br&gt;Intravaginal ovules/suppositories: 1 ovule (100 mg clindamycin) inserted intravaginally at bedtime for 3 days**&lt;br&gt;Oral†: 300 mg PO BID for 7 days**</td>
<td>See dosing regimen</td>
</tr>
<tr>
<td>metronidazole (Flagyl®, MetroGel-Vaginal®, Nuvessa®, Vandazole®)</td>
<td>0.75% vaginal gel (MetroGel-vaginal): 1 applicatorful (5 g of 0.75% metronidazole gel) intravaginally 1 to 2 times daily for 5 days&lt;br&gt;0.75% vaginal gel (Vandazole): One applicatorful (5 g of 0.75% metronidazole gel) intravaginally once daily for 5 days*&lt;br&gt;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.&lt;br&gt;Regular-release tablet†: 500 mg PO BID for 7 days*</td>
<td>See dosing regimen</td>
</tr>
<tr>
<td>tinidazole (Tindamax®)</td>
<td>2 g PO QD for 2 days or 1 g PO QD for 5 days**</td>
<td>See dosing regimen</td>
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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.<br>†Off-label indication<br>*Recommended regimen per CDC<br>**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<br>- Boxed warning(s): none reported

Appendix D: CDC Treatment Regimens for Bacterial Vaginosis
- Metronidazole 500 mg orally twice a day for 7 days
CLINICAL POLICY
Secnidazole

• 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Bacterial vaginosis</td>
<td>2 g PO as a single-dose</td>
<td>See dosing regimen</td>
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VI. Product Availability

Oral granules: 2 g

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>10.24.17</td>
<td>02.18</td>
</tr>
<tr>
<td>1Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>09.24.18</td>
<td>02.19</td>
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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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