

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

| | |
|-------------------|--|
| Program Number | 2024 P 3107-8 |
| Program | Step Therapy |
| Medication | Solosec® (secnidazole) |
| P&T Approval Date | 4/2018, 3/2019, 3/2020, 3/2021, 8/2021, 8/2022, 8/2023, 8/2024 |
| Effective Date | 11/1/2024 |

1. Background:

Solosec (secnidazole) is indicated for the treatment of bacterial vaginosis and for the treatment of trichomoniasis in patients 12 years of age and older. Solosec is available as a two gram oral granule and should be taken as a single dose.

Step therapy programs are intended to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try an alternative antibacterial agent before providing coverage for Solosec.

2. Coverage Criteria^a:

A. Authorization

1. Bacterial vaginosis

a. **Solosec** will be approved based on the following criterion:

- 1) History of failure, contraindication or intolerance to **one** of the following:
 - a) clindamycin capsules (generic Cleocin)
 - b) clindamycin vaginal cream (generic Cleocin, Clindesse)
 - c) clindamycin vaginal suppository (Cleocin)
 - d) metronidazole tablets (generic Flagyl)
 - e) metronidazole vaginal gel (Metrogel-Vaginal)
 - f) tinidazole tablets (generic Tindamax)

Authorization will be issued for one month.

2. *Trichomonas vaginalis*

a. **Solosec** will be approved based on the following criterion:

- 1) History of failure, contraindication or intolerance to **one** of the following:
 - a) metronidazole tablets (generic Flagyl)
 - b) tinidazole tablets (generic Tindamax)

Authorization will be issued for one month.

^a State mandates may apply. Any federal regulatory requirements and the member specific

benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Solosec [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; July 2022.
2. Sexually Transmitted Diseases Treatment Guidelines, 2021. Bacterial Vaginosis. Centers for Disease Control and Prevention. July 2021. [Bacterial Vaginosis - STD information from CDC](#). Accessed July 2024.
3. Sexually Transmitted Diseases Treatment Guidelines, 2021. Trichomoniasis. Centers for Disease Control and Prevention. July 2021. [Trichomoniasis - STI Treatment Guidelines \(cdc.gov\)](#). Accessed July 2024.

| Program | Step Therapy – Solosec |
|-----------------------|---|
| Change Control | |
| Date | Change |
| 4/2018 | New program. |
| 3/2019 | Annual review. Added Cleocin vaginal suppositories as a step 1 agent. Added statement regarding use of automated process. |
| 3/2020 | Annual review. Updated references. |
| 3/2021 | Annual review. Updated references. |
| 8/2021 | Added new indication for <i>Trichomonas vaginalis</i> . |
| 8/2022 | Annual review. Updated background section and references. |
| 8/2023 | Annual review. Updated references. |
| 8/2024 | Annual review. No changes. |