Pharmacy Medical Necessity Guidelines: Solosec® (secnidazole)

Effective: February 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Solosec® (secnidazole) is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in patients 12 years and older as well as the treatment of trichomoniasis in patients 12 years of age and older. 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.

COVERAGE GUIDELINES

The plan may authorize coverage of Solosec® (secnidazole) for Members when **ALL** of the following criteria are met and limitations do not apply:

Bacterial Vaginosis:

1. Member has a diagnosis of bacterial vaginosis

AND

2. The Members is 12 years of age or older

AND

3. The Member has had an inadequate response, intolerance, or contraindication, to two of the following agents: metronidazole, clindamycin, tinidazole.

Trichomoniasis:

1. Member has a diagnosis of trichomoniasis

AND

2. The Member is 12 years of age or older

AND

3. The Member has had an inadequate response, intolerance, or contraindication to both of the following: metronidazole and tinidazole

LIMITATIONS

1. Initial approval will be for 7 days.
2. Requests for continuation of therapy should be reviewed against the initial approval criteria and at least 14 days should have elapsed since the previous claim for Solosec®.

CODES

None

REFERENCES

1. Sobel J. Bacterial vaginosis: initial treatment. Available at: www.uptodate.com. Accessed 11 January 2024.
2. Solosec (secnidazole) [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; July 2022.
3. Workowski KA, Bahmann LH, Chan PA, et al. Sexually transmitted diseases treatment guidelines, 2021. MMWR. 2021;70:1-187.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective June 1, 2023, updated the age requirements to 12 years of age to be aligned with the FDA-approved package labeling.

2. February 13, 2024: Effective March 1, 2024, updated fax number for RxUM.
3. February 11, 2025: No changes
4. February 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.