

## Pharmacy Medical Necessity Guidelines: Solosec® (secnidazole)

Effective: May 12, 2020

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p><b>Fax Numbers:</b>  RXUM:  617.673.0988</p>	

**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 adult women. 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.

Solosec® should administered as a single 2-gram packet of granules once orally, without regard to the timing of meals.

### COVERAGE GUIDELINES

The plan may authorize coverage of Solosec® (secnidazole) for Members when **all** of the following criteria are met:

- Member has a diagnosis of bacterial vaginosis
- AND**
- The Members is 18 years of age or older
- AND**
- The Member has had an inadequate response, intolerance, or contraindication, to two of the following agents within the last six months: metronidazole, clindamycin, tinidazole.

### LIMITATIONS

- Initial approval will be for 7 days.
- 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

- Solosec (secnidazole) [prescribing information]. Baltimore, MD: Symbiomix Therapeutics, LLC; October 2019.
- Workowski KA, Bolan GA, Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015;64:1.

### APPROVAL HISTORY

August 7, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 11, 2019: Administrative changes made to template.
- May 12, 2020: 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.