

Solosec™ (secnidazole)

Policy # 00623

Original Effective Date: 07/11/2018

Current Effective Date: 09/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Bacterial Vaginosis

Based on review of available data, the Company may consider Solosec™[‡] (secnidazole) for the treatment of bacterial vaginosis in females to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Solosec (secnidazole) will be considered when the following criteria are met:

- Patient is a female with a diagnosis of bacterial vaginosis; AND
- Patient is 12 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following GENERIC agents FOR THE CURRENT INFECTION: metronidazole (oral or vaginal), clindamycin (oral or vaginal), or tinidazole (oral) unless there is clinical evidence or patient history that suggests the use of TWO GENERIC agents will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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Trichomoniasis

Based on review of available data, the Company may consider Solosec (secnidazole) for the treatment of trichomoniasis to be **eligible for coverage**** when the patient selection criteria are met

Patient Selection Criteria

Coverage eligibility for Solosec (secnidazole) will be considered when the following criteria are met:

- Patient has a diagnosis of trichomoniasis; AND
- Patient is 12 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH of the following GENERIC agents FOR THE CURRENT INFECTION: metronidazole (oral) and tinidazole (oral) unless there is clinical evidence or patient history that suggests the use of these GENERIC agents will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Solosec (secnidazole) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) TWO of the following GENERIC agents FOR THE CURRENT BACTERIAL VAGINOSIS INFECTION: metronidazole (oral or vaginal), clindamycin (oral or vaginal), or tinidazole (oral) to be **not medically necessary.****

Based on review of available data, the Company considers the use of Solosec (secnidazole) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) BOTH of the following GENERIC agents FOR THE CURRENT TRICHOMONIASIS INFECTION: metronidazole (oral) or tinidazole (oral) to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Solosec (secnidazole) for a non-FDA approved indication OR in patients less than 12 years of age to be **investigational.***

Background/Overview

Solosec is a nitroimidazole antimicrobial that is approved for the treatment of bacterial vaginosis in females ages 12 and older and for the treatment of trichomoniasis in patients 12 years of age and older. It is available in 2 gram unit of use child resistant foil packets. The dose is a single 2 gram packet of granules once orally for both indications. Treatment of bacterial vaginosis prior to the approval of this product included drugs such as: metronidazole (oral or vaginal), clindamycin (oral or vaginal), or tinidazole (oral), which are all available in generic form and offer an effective and economical means of treatment of bacterial vaginosis. The nitroimidazoles, metronidazole (oral) and

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tinidazole (oral), are the only class known to effectively treat trichomoniasis with metronidazole (oral) being the preferred agent. There have been no head-to-head studies to determine if Solosec is superior to any other treatment option for trichomoniasis as it has only been compared to placebo. Metronidazole (oral) and tinidazole (oral), both available in generic formulations, offer cost effective options that are equally effective in treating trichomoniasis.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Solosec was approved in late 2017 for the treatment of bacterial vaginosis in adult women. In January 2022, it was also approved for the treatment of trichomoniasis in patients 12 years of age and older and expanded its approval for bacterial vaginosis to include females 12 years of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Two randomized placebo-controlled clinical trials with similar designs were conducted to evaluate the efficacy of Solosec 2 gram for the treatment of bacterial vaginosis. In both trials, a statistically significantly greater percentage of patients experienced a clinical response. In trial 1, 67.7% of subjects were deemed clinical responders vs. 17.7% in the placebo group at 21-30 days post treatment. In trial 2, 53.3% of subjects in the Solosec group were deemed clinical responders vs. 19.3% in the placebo group at 21-30 days post treatment. At 7-14 days post treatment, 57.9% of Solosec subjects were clinical responders vs. 24.6% in the placebo group.

Efficacy of a single 2 gram dose of Solosec for the treatment of trichomoniasis was evaluated in a multi-center, randomized, placebo-controlled, delayed treatment, double blind trial. Test of cure was carried out after 6 to 12 days of initial treatment. The microbiological cure rate, which is defined as a negative test for *T. vaginalis* was significantly higher in patients who were treated with Solosec vs. placebo (92.2 vs. 1.5%).

It should be noted that this product has NOT been studied head-to-head with standards of care for bacterial vaginosis (e.g., metronidazole [oral or vaginal], clindamycin [oral or vaginal]), or tinidazole [oral]) or trichomoniasis (metronidazole [oral] or tinidazole [oral]). The generically available options represent an equally efficacious and more economical alternative to treatment for both conditions.

References

1. Solosec [package insert]. Lupin Pharma. Baltimore, Maryland. January 2022.
2. Bacterial Vaginosis Treatment. UpToDate. Accessed June 2018.
3. Trichomoniasis. UpToDate. Accessed June 2022.

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Policy History

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07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. New policy.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Added a new indication, trichomoniasis, to the policy with criteria. Updated background and regulatory approval section to reflect expanded age range approved by the FDA. Updated rationale section to include relevant study information pertaining to trichomoniasis indication.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/12/2026	Pre Pharmacy & Therapeutics Committee review.
08/19/2026	Pharmacy & Therapeutics Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.