Solosec™ (secnidazole)

Policy # 00623
Original Effective Date: 07/11/2018
Current Effective Date: 07/11/2018

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.

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.*

Based on review of available data, the Company may consider Solosec™‡ (secnidazole) for the treatment of bacterial vaginosis in adult women 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 18 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 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 INFECTION: metronidazole (oral or vaginal), clindamycin (oral or vaginal), 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 18 years of age to be **investigational.***

Background/Overview

Solosec is a nitroimidazole antimicrobial that was approved in late 2017 for the treatment of bacterial vaginosis in adult women. 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. 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

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(oral), which are all available in generic form and offer an effective and economical means of treatment of bacterial vaginosis.

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.

Rationale/Source

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

References

1. Solosec [package insert]. Lupin Pharma. Baltimore, Maryland. October 2017.
2. Bacterial Vaginosis Treatment. UpToDate. Accessed June 2018.

Policy History

Original Effective Date: 07/11/2018
Current Effective Date: 07/11/2018
07/05/2018 Medical Policy Committee review
07/11/2018 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 07/2019

*****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 diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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**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.

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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.