



# Louisiana

## **Xaciato™ (clindamycin)**

Policy # 00842

Original Effective Date: 08/14/2023

Current Effective Date: 08/12/2024

*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 Xaciato™<sup>‡</sup> (clindamycin) 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 Xaciato (clindamycin) 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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## **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of Xaciato (clindamycin) 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**.\*\*

## **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 Xaciato (clindamycin) for a non-FDA approved indication OR in patients less than 12 years of age to be **investigational**.\*

## **Background/Overview**

Xaciato is indicated for the treatment of bacterial vaginosis in females 12 years of age and older. It is available as a 2% gel in an 8 gram tube. One dose of Xaciato delivers 100 mg of clindamycin vaginally via applicator. 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.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Xaciato is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 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

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practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Xaciato as a treatment of bacterial vaginosis (BV) in females 12 years of age and older was demonstrated in a randomized, double-blind, placebo-controlled clinical study (Trial 1). A single dose of Xaciato was compared to a single dose of placebo vaginal gel for the treatment of BV. Clinical Cure was defined as resolution of the abnormal vaginal discharge associated with BV, a negative 10% KOH whiff test, and clue cells < 20% of the total epithelial cells in the saline wet mount. Bacteriological Cure was defined as a Nugent score < 4. Therapeutic Cure was defined as the presence of both a Clinical Cure and Bacteriological Cure.

In the modified Intent-To-Treat (mITT) population, a statistically significantly greater percentage of patients experienced Clinical Cure, Bacteriological Cure, and Therapeutic Cure at the Test of Cure (Day 21-30) visit in the Xaciato arm compared to placebo. Statistically significant results for the endpoints were also achieved at the Interim Assessment visit (Day 7-14). Summary of Clinical Cure, Bacteriological Cure and Therapeutic Cure can be found in the table below.

Parameter	Interim Assessment visit (Day 7-14)			Test of Cure visit (Day 21-30)		
	Xaciato n (%)	Placebo n (%)	Treatment Difference (%) [95% Confidence Interval]	Xaciato n (%)	Placebo n (%)	Treatment Difference (%) [95% Confidence Interval]
<b>Clinical Cure</b>	93 (76.2)	14 (23.7)	52.5 (38.0, 67.0)	86 (70.5)	21 (35.6)	34.9 (19.0, 50.8)
<b>Bacteriological Cure</b>	50 (41.0)	2 (3.4)	37.6 (26.5, 48.7)	53 (43.4)	3 (5.1)	38.4 (26.7, 50.1)
<b>Therapeutic Cure</b>	43 (35.2)	0	35.2 (25.5, 45.0)	45 (36.9)	3 (5.1)	31.8 (20.3, 43.3)

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It should be noted that this product has NOT been studied head-to-head with previously FDA approved standards of care for bacterial vaginosis (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 for this condition.

## **References**

1. Xaciato [package insert]. Darè Bioscience, Inc. San Diego, California. Updated March 2023.

## **Policy History**

Original Effective Date: 08/14/2023

Current Effective Date: 08/12/2024

07/06/2023 Medical Policy Committee review

07/12/2023 Medical Policy Implementation Committee approval. New policy.

07/02/2024 Medical Policy Committee review

07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2025

\*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:

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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.

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