LOUISIANA BLUE

Xdemvy™ (lotilaner ophthalmic solution)

Policy # 00866
Original Effective Date: 03/11/2024
Current Effective Date: 03/10/2025

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 the use of Xdemvy™‡ (lotilaner ophthalmic solution) to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Xdemvy will be considered when the following criteria are met:

- Patient has a diagnosis of *Demodex* blepharitis; AND
- Diagnosis has been verified by the presence of collarettes on more than 10 lashes on the upper lid; AND
  *(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.)*
- Patient is 18 years of age or older; AND
- Treatment course with Xdemvy will be limited to 6 weeks.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Xdemvy when there is no verification of the presence of collarettes on more than 10 lashes on the upper lid 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 Xdemvy (lotilaner ophthalmic solution) when patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational.***

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Background/Overview

Xdemvy is an ophthalmic solution containing 0.25% lotilaner, a gamma-aminobutyric acid (GABA)-gated chloride channel inhibitor selective for mites. Inhibition of these GABA chloride channels causes a paralytic action in the target organism leading to its death. For the treatment of *Demodex* blepharitis, patients should instill one drop of Xdemvy into each eye twice daily (approximately 12 hours apart) for 6 weeks. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Demodex blepharitis is a common inflammatory eyelid margin disease characterized by erythema, ocular irritation, discharge, and debris on the eyelids and lashes. It is associated with an infestation with *Demodex* mites, which are ectoparasites commonly found on human skin. Blepharitis due to *Demodex* mites is often overlooked or undiagnosed. The prevalence of *Demodex* blepharitis is unknown but may impact around 1 million to up to 25 million people in the U.S.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Xdemvy was approved in July 2023 for the treatment of *Demodex* blepharitis.

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.

The safety and efficacy of Xdemvy for the treatment of *Demodex* blepharitis was evaluated in a total of 833 patients (415 of which received Xdemvy) in two 6-week, randomized, multicenter, double-masked, vehicle-controlled studies (Saturn-1 and Saturn-2). Patients with *Demodex* blepharitis were randomized to either Xdemvy or Vehicle at a 1:1 ratio dosed twice daily in each eye.

Efficacy was demonstrated by improvement in lids (Reduction of collarettes to no more than 2 collarettes per upper lid) in each study by Day 43. In Saturn-1, 44% of patients met this endpoint in the Xdemvy group compared to 7% in the vehicle group. In Saturn-2, 55% of patients met this endpoint compared to 12% in the placebo group at Day 43.

References

1. Xdemvy [package insert]. Tarsus Pharmaceuticals, Inc. Irvine, CA. Updated July, 2023.
2. Xdemvy Drug Evaluation. Express Scripts. Updated August, 2023.

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Policy History

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02/01/2024 Medical Policy Committee review
02/14/2024 Medical Policy Implementation Committee approval. New policy.
02/06/2025 Medical Policy Committee review
02/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 02/2026

*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 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.