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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	September 8, 2023
Subject:	Xdemvy	**Page:**	1 of 4

Last Review Date: December 13, 2024

Xdemvy

Description

Xdemvy (lotilaner) ophthalmic solution

Background
Xdemvy (lotilaner) is 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. Xdemvy is not an inhibitor of mammalian GABA mediated chloride channels when tested at up to 18 µg/mL *in vitro* (1).

Regulatory Status
FDA-approved indication: Xdemvy is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis (1).

Xdemvy contains warnings regarding risk of contamination and use with contact lenses. The tip of the dispensing container should not be allowed to touch the eye, surrounding structures, fingers, or other surfaces in order to minimize contamination of the solution. Contact lenses should be removed prior to instillation of Xdemvy and may be reinserted 15 minutes following its administration (1).

Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xdemvy may be considered **medically necessary** if the conditions indicated below are met.

Xdemvy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Demodex blepharitis

AND ALL of the following:

1. Presence of *Demodex* mites has been confirmed
2. Prescriber has determined the presence and density of *Demodex* mites is causing or contributing to the patient's blepharitis symptoms
3. Patient remains symptomatic for *Demodex* blepharitis after an adequate trial of **ONE** of the following:
    a. Eye lid hygiene regimen (e.g., lid scrubbing wipes, debridement)
    b. Topical tea tree oil
4. Prescribed by or in consultation with an optometrist, ophthalmologist, dermatologist, or a specialist in the treatment of the patient's diagnosis

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 bottles

Duration 12 months

Every 12 months patient may be approved for a quantity sufficient for 24 weeks of therapy

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Xdemvy is an anti-parasitic indicated for the treatment of Demodex blepharitis. Xdemvy is selective for GABA chloride channels in mites. Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xdemvy while maintaining optimal therapeutic outcomes.

References

1. Xdemvy [package insert]. Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review
August 2024	For operational consistency, changed quantity limit to 4 bottles per 12 months
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.