Clinical Policy: Lotilaner (Xdemvy)

Reference Number: PA.CP.PMN.291
Effective Date: 12/2023
Last Review Date: 10/2025

Description
Lotilaner (Xdemvy™) is an extoparasiticide.

FDA Approved Indication(s)
Xdemvy is indicated for the treatment of Demodex blepharitis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Xdemvy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Demodex Blepharitis (must meet all)**:**

1. Diagnosis of Demodex blepharitis;
2. Prescribed by or in consultation with an optometrist or ophthalmologist;
3. Age ≥ 18 years;
4. Request does not exceed 1 bottle per 6 weeks.

Approval duration: 6 weeks

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Demodex Blepharitis:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Demodex blepharitis	1 drop BID in each eye approximately 12 hours apart	2 drops/day in each eye

VI. Product Availability

Ophthalmic solution: 0.25%, 10 mL total

VII. References

1. Xdemvy Prescribing Information. Irvine, CA: Tarsus Pharmaceuticals, Inc; July 2023. Available at: www.xdemvy.com. Accessed August 5, 2025.
2. Donnenfeld E, Nichols KK, Ayres BD, et al. The Demodex Expert Panel on Treatment and Eyelid Health (DEPTH) consensus regarding the preferred treatment for Demodex blepharitis. Clin Ophthalmol. 2025 Jun 18;19:1893-1904. doi: 10.2147/OPTH.S525681.Lin A, Ahmad S, Amescua G, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Blepharitis Preferred Practice Pattern. Ophthalmology. 2023 Feb; 131 (4): P50-P86 doi: 10.1016/j.ophtha.2023.12.036
3. Shah PP, Stein RL, Perry HD. Update on the management of demodex blepharitis. Cornea. 2022;41:934-939.

Reviews, Revisions, and Approvals	Date
Policy created	10/2023
4Q 2024 annual review: no significant changes; references reviewed and updated.	10/2024
4Q 2025 annual review: added optometrist or ophthalmologist prescriber requirement; references reviewed and updated.	10/2025