Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Xdemvy (lotilaner ophthalmic solution)

Effective: March 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Xdemvy (lotilaner ophthalmic solution) is an ectoparasiticide (antiparasitic) indicated for the treatment of Demodex blepharitis.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xdemvy for patients when **ALL** of the following criteria are met:

Initial therapy:

1. Documented diagnosis of Demodex blepharitis as determined by all of the following:
    a. Presence of at least mild erythema of the upper eyelid margin
    b. Presence of mites upon examination of eyelashes or presence of collarettes on more than 10 lashes

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by an optometrist or ophthalmologist

Reauthorization:

1. Initial criteria are met

AND

2. The most recent treatment with Xdemvy was started no sooner than six (6) months ago.

Limitations

- Duration of initial approval for Xdemvy is limited to 6 weeks. Duration of reauthorization is limited to 6 weeks. Coverage is limited to no more than one treatment course per 6 months.
- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization

Codes

None

References

1. Xdemvy (lotilaner) [prescribing information]. Irvine, CA: Tarsus Pharmaceuticals Inc; July 2023.
2. Amescua, Guillermo, et al. "Blepharitis preferred practice pattern®." *Ophthalmology* 126.1 (2019): P56-P93.

3. Ayres, Brandon D., et al. "Clinical diagnosis and management of Demodex blepharitis: the Demodex Expert Panel on Treatment and Eyelid Health (DEPTH)." Eye (2023): 1-7.
4. Shah, Paras P., Rebecca L. Stein, and Henry D. Perry. "Update on the management of demodex blepharitis." *Cornea* 41.8 (2022): 934-939.
5. Fromstein, Stephanie R., et al. "Demodex blepharitis: clinical perspectives." *Clinical Optometry* (2018): 57-63.
6. Navel, Valentin, et al. "Efficacy of treatments for Demodex blepharitis: a systematic review and meta-analysis." *The ocular surface* 17.4 (2019): 655-669.
7. Shtein RM. Blepharitis. UpToDate. In: UpToDate, Givens J (ed), Waltham, MA, 2023.

Approval And Revision History

January 9, 2024: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guideline effective February 1, 2024.

Subsequent endorsement date(s) and changes made:

- January 14, 2025: no changes.
- February 10, 2026: no changes.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.