Pharmacy Medical Necessity Guidelines:
Xdemvy (lotilaner ophthalmic solution)

Effective: January 13, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Xdemvy (lotilaner ophthalmic solution) is an ectoparasiticide (antiparasitic) indicated for the treatment of Demodex blepharitis. Xdemvy is administered in each eye twice daily for six weeks.

COVERAGE GUIDELINES

The plan may authorize coverage of a Xdemvy when 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

1. 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.
2. Xdemvy is limited to a quantity of one bottle per fill and two fills per year.

CODES

None

REFERENCES

1. Amescua, Guillermo, et al. "Blepharitis preferred practice pattern®." *Ophthalmology* 126.1 (2019): P56-P93.
2. 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.
3. Shah, Paras P., Rebecca L. Stein, and Henry D. Perry. "Update on the management of demodex blepharitis." *Cornea* 41.8 (2022): 934-939.
4. Fromstein, Stephanie R., et al. "Demodex blepharitis: clinical perspectives." *Clinical Optometry* (2018): 57-63.
5. Navel, Valentin, et al. "Efficacy of treatments for Demodex blepharitis: a systematic review and meta-analysis." *The ocular surface* 17.4 (2019): 655-669.
6. Shtein RM. Blepharitis. UpToDate. In: UpToDate, Givens J (ed), Waltham, MA, 2023.
7. Xdemvy (lotilaner) [prescribing information]. Irvine, CA: Tarsus Pharmaceuticals Inc; August 2024.

APPROVAL HISTORY

January 9, 2024: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

1. January 14, 2025: No changes
2. January 13, 2026: No changes

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.

Provider Services