

Applicable Drugs: Xdemvy (lotilaner)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: 2/20/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to VII are met)

- I. Diagnosis of *Demodex* blepharitis and the following criteria A and B are met:
 - A. Documented presence of > 10 collarettes present on the upper lid on slit lamp examination.
 - B. Documented presence of at least mild erythema of the upper eyelid margin.
- II. Documented moderate to severe blepharitis symptoms or architectural changes associated with *Demodex* infestation that interfere with daily life (eg, ocular irritation, itching, dryness, tearing, foreign body sensation, trichiasis, eyelash loss).
- III. Minimum age requirement: 18 years old.
- IV. Documentation that the patient is practicing good eyelid hygiene and continues to be symptomatic after a trial or contraindication to eyelid scrubs and tea tree oil.
- V. Treatment is prescribed by or in consultation with an ophthalmologist or optometrist.
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One 10 ml bottle per 42-day supply for a one-time fill.

APPROVAL LENGTH

- **Authorization:** One 42-day treatment course.
- **Re-Authorization:** N/A: The safety and effectiveness of Xdemvy use beyond 42 days in a single treatment course have not been evaluated.

APPENDIX

N/A

REFERENCES

1. Xdemvy. Prescribing Information. Tarsus Pharmaceuticals, Inc; 2023. Accessed February 19, 2026. <https://tarsusrx.com/wp-content/uploads/XDEMVEY-Prescribing-Information-24JUL23.pdf>
2. Yeu E, Wirta DL, Karpecki P, Baba SN, Holdbrook M; Saturn I study group. Lotilaner ophthalmic solution, 0.25%, for the treatment of Demodex blepharitis: results of a prospective, randomized, vehicle-controlled, double-masked, pivotal trial (Saturn-1). *Cornea*. 2023;1;42(4):435-443. doi: 10.1097/ICO.0000000000003097
3. Gaddie IB, Donnenfeld ED, Karpecki P, et al. Lotilaner ophthalmic Solution 0.25% for Demodex blepharitis: randomized, vehicle-controlled, multicenter, phase 3 trial (Saturn-2). *Ophthalmology*. 2023;130(10):1015-1023. doi:10.1016/j.opthta.2023.05.030
4. Lin A, Ahmad S, Amescua G, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Blepharitis preferred practice pattern. *Ophthalmology*. 2024;131(4):P50-P86. doi:10.1016/j.opthta.2023.12.036
5. Rhee MK, Yeu E, Barnett M, et al. Demodex blepharitis: a comprehensive review of the disease, current management, and emerging therapies. *Eye Contact Lens*. 2023;49(8):311-318. doi:10.1097/ICL.0000000000001003

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.