

Generic Name lotilaner

Therapeutic Class or Brand Name: Xdemvy

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/26/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

- I. Diagnosis of *Demodex* blepharitis and the following criteria A through C are met:
 - A. Documented presence of *Demodex* mites upon examination of eyelashes by light microscopy with an average density of ≥ 1.5 mites per lash (upper and lower eyelids combined).
 - B. Documented presence of > 10 collarettes present on the upper lid on slit lamp examination.
 - C. 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. The request is for a medication with the appropriate FDA labeling or current clinical practice guidelines supporting its use.

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 Xdemy use beyond 42 days in a single treatment course have not been evaluated

APPENDIX

N/A

REFERENCES

1. Xdemy. Prescribing Information. Tarsus Pharmaceuticals, Inc; 2023. Accessed June 15, 2024. <https://tarsusrx.com/wp-content/uploads/XDEMZY-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 Apr 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.ophtha.2023.05.030
4. Lin A, Ahmad S, Amescua G, et al. Blepharitis preferred practice pattern. *Ophthalmology*. 2024;131(4):P50-P86. doi:10.1016/j.ophtha.2023.12.036
5. Ayres BD, Donnenfeld E, Farid M, et al. Clinical diagnosis and management of Demodex blepharitis: the Demodex expert panel on treatment and eyelid health (DEPTH). *Eye (Lond)*. 2023;37(15):3249-3255. doi:10.1038/s41433-023-02500-4
6. Rhee MK, Yeu E, Barnett M, et al. Demodex blepharitis: 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.