MEDICAL MUTUAL®

Drug Policy

Policy:	Xdemvy (lotilaner ophthalmic solution)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Xdemvy is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis.

POLICY STATEMENT

This policy involves the use of Xdemvy. Prior authorization is recommended for pharmacy benefit coverage of Xdemvy. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xdemvy as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Xdemvy be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xdemvy is recommended in those who meet the following criteria:

1. **Demodex blepharitis**
   Criteria. *Approve for 45 days if the patient meets the following criteria (A, B, C, D, E, and F):*
   - A. Patient is ≥ 18 years old; AND
   - B. Patient has a diagnosis of Demodex blepharitis; AND
   - C. Diagnosis has been verified by the presence of collarettes on more than 10 lashes on the upper lid and presence of at least mild erythema on the upper eyelid margin [documentation required]; AND
   - D. Patient has moderate to severe blepharitis symptoms that interfere with daily life*; AND
     Note: Symptoms that interfere with daily life include but are not limited to ocular irritation, itching, dryness, or visual disturbances; AND
   - E. Patient's symptoms persist despite treatment with warm compress, eyelid cleansing, and/or artificial tears; AND
   - F. Xdemvy is prescribed by or in consultation with an optometrist or ophthalmologist.

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Initial Approval/ Extended Approval.
Approval duration: 45 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xdemvy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 2, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. American Academy of Ophthalmology (AAO). Preferred Practice Pattern: Blepharitis. 2018. Available at: https://www.aao.org/preferred-practice-pattern/blepharitis-ppp-2018
5. 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 Jun 5:S0161-6420(23)00392-5. doi: 10.1016/j.ophtha.2023.05.030. Epub ahead of print.
6. Yeu E, Wirta DL, Karpecki P, et al. 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. Epub 2022 Aug 10. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9973441/ Accessed August 2, 2023