Iowa Medicaid
IOWA HHS

# PDL DRUG REVIEW

## Proprietary Name: Xdemvy®
## Common Name: lotilaner ophthalmic solution
## PDL Category: Ophthalmics

**Pharmacology/Usage:** Lotilaner, the active ingredient of Xdemvy®, is a member of the isoxazoline family of compounds. It is a gamma-aminobutyric acid (GABA)-gated chloride channel inhibitor selective for mites. Inhibition of these GABA chloride channels causes a paralytic action in the target organism leading to its death.

**Indication:** For the treatment of Demodex blepharitis.

There is no pregnancy category for this medication; however, the risk summary indicates that there are no available data on use in pregnant women to inform any drug associated risk; however, systemic exposure to lotilaner from ocular administration is low. The safety and efficacy of use in the pediatric population have not been established.

**Dosage Form:** Ophthalmic Solution: 0.25% (2.5mg/ml).

**Recommended Dosage:** Instill one drop in each eye BID (about 12 hours apart) for 6 weeks.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart. If one dose is missed, treatment should continue with the next scheduled dose.

Contact lenses should be removed prior to instillation of Xdemvy® and may be reinserted 15 minutes following its administration.

**Drug Interactions:** There are no drug interactions listed with this product.

**Box Warning:** There is no box warning listed with this product.

**Common Adverse Drug Reactions:** *Listed % incidence for adverse drug reactions= reported % incidence for drug (Xdemvy®). Please note that there was no placebo data provided in the prescribing information to compare with.* The most frequently reported ocular adverse events included instillation site stinging and burning, which was reported in 10% of patients. Other ocular adverse reactions reported in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

**Contraindications:** There are no contraindications listed with this product.

**Manufacturer:** Tarsus Pharmaceuticals, Inc.

**Analysis:** The safety and efficacy of Xdemvy® for the treatment of Demodex blepharitis were assessed in two randomized, multicenter, double-masked, vehicle-controlled studies (Saturn-1 and Saturn-2) that were of 6 weeks duration. Patients (N=833) were randomized to either Xdemvy® or vehicle dosed twice daily in each eye.

Efficacy was demonstrated by improvement in lids (reduction of collarettes to no more than 2 collarettes per upper lid) in each study by day 43. The following table includes the proportion of patients with 2 or less collarettes for the upper eyelid between treatment groups.

| | Study 1 (Saturn-1) | | Study 2 (Saturn-2) | |
|---|---|---|---|---|
| | Xdemvy® | Vehicle | Xdemvy® | Vehicle |
| Day 8 | 2% | 2% | 4% | 3% |
| Day 15 | 10% | 1% | 18% | 4% |
| Day 22 | 18% | 2% | 28% | 6% |
| Day 43 (Primary endpoint) | 44% | 7% | 55% | 12% |
| p-value & NNT (*calculated by CHC*) for primary endpoint | p<0.01; NNT 3 | | p<0.01; NNT 3 | |

The endpoints of mite eradication (mite density of 0 mites/lash) and erythema cure (Grade 0) of Xdemvy® vs vehicle demonstrated statistically significant improvement at day 43 across both studies. The table below, which was adapted from the prescribing information, illustrates these results.

| | Study 1 (Saturn-1) | | | Study 2 (Saturn-2) | | |
|---|---|---|---|---|---|---|
| | Xdemvy® (N=212) | Vehicle (N=209) | p-value | Xdemvy® (N=203) | Vehicle (N=209) | p-value |
| Mite Eradication | 68% | 17% | <0.01 | 50% | 14% | <0.01 |
| NNT *calculated by CHC* | 2 | | | 3 | | |
| Erythema Cure | 19% | 7% | <0.01 | 30% | 9% | <0.01 |
| NNT *calculated by CHC* | 9 | | | 5 | | |

**Place in Therapy:** Xdemvy® is indicated for the treatment of Demodex blepharitis. The safety and efficacy of Xdemvy® were assessed in 2 double-blind, randomized, vehicle-controlled studies, with the primary endpoint of both studies being improvement in lids (reduction of collarettes [crusties] to no more than 2 collarettes per upper lid) by day 43. In both studies, Xdemvy® was significantly more effective than vehicle for the primary endpoint. In addition, Xdemvy® was significantly more effective than vehicle for mite eradication and erythema cure in both studies. It is currently the only FDA-approved treatment for Demodex blepharitis.

It is recommended that Xdemvy® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

**PDL Placement:** ☐ **Preferred**
☒ **Non-Preferred**

## References

[1] Xdemvy [package insert]. Irvine, CA: Tarsus Pharmaceuticals, Inc; 2023.