

## Xdemvy (lotilaner)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Blepharitis is an inflammation of the eyelid margins. It's often marked by symptoms like red, watery eyes, a burning or stinging sensation, eyelid itchiness, and red or swollen eyelids. Some patients may notice unusual eyelash growth patterns, eyelash loss, or a crusty buildup around the lashes.

A significant cause of blepharitis is the infestation of eyelash follicles and meibomian glands by tiny parasitic mites, mainly of the species *Demodex folliculorum* and *Demodex brevis*. This specific condition, termed *Demodex* blepharitis, features symptoms like redness, inflammation, abnormal eyelash growth, itching at the eyelid base, and the presence of collarettes. However, many individuals infested with *Demodex* mites do not exhibit any symptoms.

- *Demodex folliculorum* tends to infest the base of the eyelash, leading to anterior *Demodex* blepharitis, while *Demodex brevis* colonizes the meibomian glands, leading to posterior *Demodex* blepharitis.

- Traditional treatment methods have included tea tree oil, but its effectiveness remains under-researched.

Xdemvy (lotilaner ophthalmic solution) 0.25% is a topical solution is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis.

## Definitions

**“Blepharitis”** is an ocular condition characterized by the inflammation of the margins of the eyelids.

**“Collarettes”** are cylindrical dandruff or scaly debris found at the base of eyelashes, often seen in cases of Demodex blepharitis.

**“Demodex blepharitis”** is a specific type of blepharitis caused by the infestation of Demodex mites, marked by symptoms such as redness, inflammation, abnormal eyelash growth, and itching at the eyelid base.

**“Demodex folliculorum and Demodex brevis”** are two species of tiny parasitic mites that can infest the human eyelash follicles and meibomian glands, often leading to a type of blepharitis.

**“Ectoparasiticideis”** a type of medication used to kill external parasites.

**“Epilated lash”** is an eyelash that has been plucked or removed.

**“Madarosis”** refers to the loss of eyelashes.

**“Microscopic examination”** is a method to analyze samples under a microscope to identify and diagnose various conditions, such as the presence of mites.

## Medical Necessity Criteria for Initial Authorization

The Plan considers **Xdemvy (lotilaner)** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
2. The member is 18 years of age or older; **AND**
3. The member has a diagnosis of Demodex blepharitis based on the presence of clinical signs such as collarettes, lid erythema, madarosis, and/or misdirected lashes; **AND**

4. Documentation indicating that the patient has symptoms attributable to Demodex blepharitis in at least one eye (e.g. itching, foreign body sensation, burning, etc); **AND**
5. The member has **NOT** undergone more than one 6-week treatment course in the past 12 months.

**If the above prior authorization criteria are met, Xdemvy (lotilaner) will be approved for 6-weeks.**

### Medical Necessity Criteria for Reauthorization

All reauthorization requests will be reviewed on a case-by-case basis to determine if retreatment of therapy is medically necessary (based on the documentation provided, current treatment guidelines, and individual member needs). The following clinical chart documentation should be provided for review:

1. Current clinical documentation supporting the need for retreatment.
2. Documented response to the previous course of treatment.

*Documentation should indicate that the member has experienced an improvement in signs and symptoms of Demodex blepharitis with previous course of therapy (e.g., minimal to no itching, minimal to no lid erythema, and/or a decrease in collarettes compared to baseline)*

3. Plan for the duration of the treatment course.

*The benefits of a longer treatment course beyond 6-weeks are unknown.*

### Experimental or Investigational / Not Medically Necessary

Xdemvy (lotilaner) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

### References

1. Epstein, Ilan J. MD\*; Rosenberg, Eric DO†; Stuber, Ross BA‡; Choi, Michael B. MD\*; Donnenfeld, Eric D. MD\*,§; Perry, Henry D. MD\*,§,‡. Double-Masked and Unmasked Prospective Study of Terpinen-4-ol Lid Scrubs With Microblepharoexfoliation for the Treatment of Demodex Blepharitis. *Cornea* 39(4):p 408-416, April 2020. | DOI: 10.1097/ICO.0000000000002243
2. American Academy of Ophthalmology. Blepharitis Preferred Practice Pattern. Published:October 23, 2018 | DOI:<https://doi.org/10.1016/j.optha.2018.10.019>
3. Epstein IJ, Rosenberg E, Stuber R, Choi MB, Donnenfeld ED, Perry HD. Double-masked and unmasked prospective study of terpinen-4-ol lid scrubs with microblepharoexfoliation for the treatment of demodex blepharitis. *Cornea* 2020;39;408-416.

4. Randon M, Liang H, El Hamdaoui M, Tahiri R, Batellier L, Denoyer A, Labbé A, Baudouin C. In vivo confocal microscopy as a novel and reliable tool for the diagnosis of Demodex eyelid infestation. *Br J Ophthalmol* 2015;99:336-341.
5. Savla K, Le JT, Pucker AD. Tea tree oil for Demodex blepharitis. *Cochrane Database of Systematic Reviews* 2020, Issue 6. Art. No.: CD013333. DOI: 10.1002/14651858.CD013333.pub2. Accessed 24 August 2023.
6. Shah PP, Stein RL, Perry HD. Update on the Management of Demodex Blepharitis. *Cornea*. 2022 Aug 1;41(8):934-939. doi: 10.1097/ICO.0000000000002911. Epub 2021 Nov 3. PMID: 34743107.
7. 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; 42:435.
8. Zhao YE, Wu LP, Hu L, Xu JR. Association of blepharitis with Demodex: a meta-analysis. *Ophthalmic Epidemiol* 2012;19:95-102.

#### Clinical Guideline Revision / History Information

Original Date: 9/21/2023

Reviewed/Revised: