

Federal Employee Program.

XDEMVY (lotilaner) ophthalmic solution

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xdemvy (lotilaner) 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. Xdemvy is not an inhibitor of mammalian GABA mediated chloride channels when tested at up to 18 µg/mL *in vitro* (1).

Regulatory Status

FDA-approved indication: Xdemvy is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis (1).

Xdemvy contains warnings regarding risk of contamination and use with contact lenses. The tip of the dispensing container should not be allowed to touch the eye, surrounding structures, fingers, or other surfaces in order to minimize contamination of the solution. Contact lenses should be removed prior to instillation of Xdemvy and may be reinserted 15 minutes following its administration (1).

Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Summary

Xdemvy is an anti-parasitic indicated for the treatment of Demodex blepharitis. Xdemvy is selective for GABA chloride channels in mites. Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xdemvy while maintaining optimal therapeutic outcomes.

References

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