CVS Caremark®

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| Reference number(s) |
| 2869-A |

# Specialty Guideline Management Oxervate

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Oxervate | cenegermin-bkbj |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

Oxervate is indicated for the treatment of neurotrophic keratitis.

All other indications are considered experimental/investigational and not medically necessary.

## Prescriber Specialties

This medication must be prescribed by or in consultation with an ophthalmologist or optometrist.

## Coverage Criteria

### Neurotrophic Keratitis1-3

Authorization of 16 weeks (8 weeks total therapy per eye) may be granted for treatment of stage 2 and stage 3 neurotrophic keratitis when all of the following criteria are met:

* The member must experience persistent epithelial defects (PED) or corneal ulceration of at least 2 weeks duration refractory to one or more conventional non-surgical treatments (e.g., preservative free artificial tears).
* There is evidence of decreased corneal sensitivity (e.g., cotton swab method, Cochet-Bonnet contact aesthesiometer, CRCERT-Belmonte non-contact aesthesiometer) within the area of the PED or corneal ulcer and outside of the area of the defect in at least one corneal quadrant.
* The member has not received a previous 8-week course of Oxervate in the affected eye.

## References

1. Oxervate [package insert]. San Mateo, CA: Dompe U.S. Inc.; December 2024.
2. Bonini S, Lambiase A, Rama P, et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. Opthalmol. 2018;125(9):1332-1343. doi: 10.1016/j.ophtha.2018.02.022
3. Cunha AN, Bunya VY, Woodward MA, et al. Neurotrophic keratitis. American Academy of Ophthalmology EyeWiki. Updated June 18, 2024. Accessed October 9, 2024. <https://eyewiki.aao.org/Neurotrophic_Keratitis>.