

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Oxervate under the patient's prescription drug benefit.

Description:

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 Indication

Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

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

Applicable Drug List:

Oxervate

Policy/Guideline:

Criteria for Initial Approval: Neurotrophic keratitis

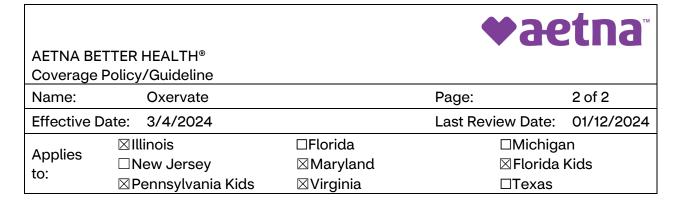
Authorization of 8 weeks total per eye may be granted for treatment of Stage 2 and Stage 3 neurotrophic keratitis when all the following criteria are met:

- A. The member must experience persistent epithelial defects (PED) or corneal ulceration of at least 2 weeks duration refractory to one or more conventional nonsurgical treatments (e.g., preservative free artificial tears).
- B. 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.
- C. The member has not received a previous 8-week course of Oxervate in the affected eye.

Approval Duration and Quantity Restrictions:

Approval: 8 weeks total per eye

Quantity Level Limit: Oxervate 0.002% ophthalmic solution, carton containing 7 vials (1 mL in each vial): 16 cartons (112 mL) per 56 days



References:

- 1. Oxervate [package insert]. Boston, MA: Dompe U.S. Inc.; October 2019.
- 2. Bonini S, Lambiase A, Rama P, et al. Phase II randomized, double-masked, vehiclecontrolled trial of recombinant human nerve growth factor for neurotrophic keratitis. *Opthalmol.* 2018;125(9):1332-433.
- 3. Bunya VY, Woodward MA, Rabiolo A, et al. Neurotrophic Keratitis. Neurotrophic Keratitis. American Academy of Ophthalmology. Published December 30, 2021. Available at: https://eyewiki.aao.org/Neurotrophic_Keratitis. Accessed October 12, 2023.