

SPECIALTY GUIDELINE MANAGEMENT

OXERVATE (cenegermin-bkbj)

POLICY

I. 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 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.

II. 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 of 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 non-surgical 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.

REFERENCES

1. Oxervate [package insert]. Boston, MA: Dompe U.S. Inc.; October 2019.
2. Evaluation of Safety and Efficacy of rhNGF in Patients With Stage 2 and 3 Neurotrophic Keratitis. (REPARO). Available at: <https://clinicaltrials.gov/ct2/show/NCT01756456>. Accessed October 4, 2022.
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, 2022.