Reference number(s)
2869-A

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 (less than or equal to 4 cm using the Cochet-Bonnet 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 19, 2021.