

Generic Name: Cenegermin-bkbj

Therapeutic Class or Brand Name: Oxervate

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/24/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of neurotrophic keratitis (NK) and meets ALL the criteria below:
 - A. Diagnosis of Stage 2 (persistent epithelial defect [PED]) OR Stage 3 (corneal ulcer) NK.
 - B. Treatment failure, intolerance, or contraindication to the following conventional non-surgical treatments (i AND ii):
 - i. One over-the-counter artificial tear product (e.g., Systane, Refresh, TheraTears, GenTeal, etc.).
 - ii. Therapeutic (bandage) contact lenses.
 - C. Contraindication to surgical procedures (e.g., amniotic membrane transplantation, surgical tarsorrhaphy, etc.).
 - D. Documented specific eye(s) intended for treatment.
- II. Minimum age requirement: 2 years old.
- III. Treatment must be prescribed by or in consultation with an ophthalmologist or optometrist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One affected eye: 28 vials per 28 days

- Two affected eyes: 56 vials per 28 days

APPROVAL LENGTH

- **Authorization:** 8 weeks
- **Re-Authorization:** 8 weeks. Maximum treatment duration is 16 weeks per eye.
 - Renewal may be considered on a case-by-case basis with documentation of continued indicators of active disease (e.g., neurotrophic lesions, positive response to therapy, and absence of clinically significant adverse events).

APPENDIX

- N/A

REFERENCES

1. Oxervate. Prescribing information. Dompé farmaceutici S.p.A.; August 2018. Accessed January 12, 2025. <https://oxervate.com/wp-content/uploads/2024/12/OXERVATE-PI-Rev.-12-2024.pdf>
2. Dana R, Farid M, Gupta PK, et al. Expert consensus on the identification, diagnosis, and treatment of neurotrophic keratopathy. BMC Ophthalmology. 2021;21(1):327-335. doi:<https://doi.org/10.1186/s12886-021-02092-1>

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.