

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Oxervate (cenegermin-bkbj)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 8 kits per eye for 8 weeks (per lifetime)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Oxervate (cenegermin-bkbj) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

NEUROTROPHIC KERATITIS

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an ophthalmologist or neurologist; AND
2. Member has a diagnosis of stage 2 (persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis, confirmed by a corneal sensitivity test (documentation required); AND
3. Member has had a trial and failure of preservative-free artificial tears for at least 14 days (with progression of corneal damage); AND
4. Member does NOT have severe corneal thinning (i.e., involving posterior third of the stroma), corneal melting or perforation in the affected eye.
5. **Dosage allowed:** 1 drop to affected eye(s) 6 times per day (2-hour intervals).

If member meets all the requirements listed above, the medication will be approved for 8 weeks.

For **reauthorization**: Not applicable. There is insufficient data to support re-treatment of the same eye.

CareSource considers Oxervate (cenegermin-bkbj) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/16/2020	New policy for Oxervate created.

References:

1. Oxervate® (cenegermin-bkbj) [package insert]. Boston, MA: Dompe U.S. Inc; 2019.
2. Wells J. Diagnosing and Treating Neurotrophic Keratopathy. *EyeNet Magazine*. 2008. <https://www.aao.org/eyenet/article/diagnosing-treating-neurotrophic-keratopathy?julyaugust-2008>. Accessed September 18, 2020.
3. Lambiase A, Sacchetti M. Diagnosis and management of neurotrophic keratitis. *Clinical Ophthalmology*. 2014;571-579. doi:10.2147/oph.s45921

4. Evaluation of Safety and Efficacy of rhNGF in Patients With Stage 2 and 3 Neurotrophic Keratitis. (REPARO). ClinicalTrials.gov Identifier: NCT01756456. Updated July 29, 2019. Accessed September 18, 2020. <https://clinicaltrials.gov/ct2/show/NCT01756456>
5. Sheha H, Tighe S, Hashem O, Hayashida Y. Update On Cenergermin Eye Drops In The Treatment Of Neurotrophic Keratitis. *Clinical Ophthalmology*. 2019:1973-1980. doi:10.2147/oph.s185184
6. Fleeman N, Mahon J, Nevitt S, et al. Cenergermin for Treating Neurotrophic Keratitis: An Evidence Review Group Perspective of a NICE Single Technology Appraisal. *PharmacoEconomics - Open*. 2019;3(4):453-461. doi:10.1007/s41669-019-0138-z
7. Pflugfelder SC, Massaro-Giordano M, Perez VL, et al. Topical Recombinant Human Nerve Growth Factor (Cenergermin) for Neurotrophic Keratopathy. *Ophthalmology*. 2020;127(1):14-26. doi:10.1016/j.ophtha.2019.08.020
8. Deeks ED, Lamb YN. Cenergermin: A Review in Neurotrophic Keratitis. *Drugs*. 2020;80(5):489-494. doi:10.1007/s40265-020-01289-w

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