

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 **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. Member is 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist or neurologist; AND
3. 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
4. Member has not received 8 weeks or more of prior cenegermin treatment for 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.
11/18/2021	Removed trial and failure of artificial tears and requirement that member does not have severe corneal thinning or melting, or perforation in affected eye. Added age limit and requirement that member has not received previous cenegermin treatment.

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

Effective date: 01/01/2022

Revised date: 11/18/2021