CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Oxervate (cenegermin-bkbj)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Oxervate, approved by the FDA in 2018, is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). It is supplied as a 0.002% ophthalmic solution in multidose vials. NK is a rare, degenerative disease of the cornea caused by damage of the trigeminal nerve, which results in corneal epithelial breakdown, impairment of corneal healing, and development of ulceration, melting, and perforation. The hallmark of NK is a decrease or absence of corneal sensation. There are 3 stages of NK, with stage 1 being the mildest. Treatments are based on the staging. Left untreated, vision loss can occur. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity. Oxervate directly promotes corneal healing.

Oxervate (cenegermin-bkbj) will be considered for coverage when the following criteria are met:

Neurotrophic Keratitis (NK)

For **initial** authorization:

1. Member must be 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 had a trial and failure of preservative-free artificial tears for at least 14 days (with progression of corneal damage); AND
5. Member does NOT have severe corneal thinning (i.e., involving posterior third of the stroma), corneal melting or perforation in the affected eye.
6. **Dosage allowed/Quantity limit:**
   1 drop to affected eye(s) 6 times per day at 2-hour intervals for 8 weeks.
   QL: 8 kits per eye for 8 weeks (per lifetime)

If all the above requirements are met, 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 conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/16/2020	New policy for Oxervate created.
02/23/2022	Transferred to new template. Annual review; no changes.
05/13/2024	Updated references.

References:

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4. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol*. 2014;8:571-579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921
5. Sheha H, Tighe S, Hashem O, Hayashida Y. Update On Cenegermin Eye Drops In The Treatment Of Neurotrophic Keratitis. *Clinical Ophthalmology*. 2019:1973-1980. doi:10.2147/opth.s185184
6. Fleeman N, Mahon J, Nevitt S, et al. Cenegermin 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
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9. Dana R, Farid M, Gupta PK, et al. Expert consensus on the identification, diagnosis, and treatment of neurotrophic keratopathy. *BMC Ophthalmol*. 2021;21(1):327. Published 2021 Sep 8. doi:10.1186/s12886-021-02092-1

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