

Policy Name:	Oxervate (cenegermin)	Policy #:	2712P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Oxervate.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Oxervate when the following criteria for coverage have been met.

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of Stage 2 or Stage 3 neurotrophic keratitis, with decreased or absent corneal sensation, including which eye(s) is/are affected
- 1.2 Prescribed by or in consultation with an ophthalmologist (eye doctor) with expertise in corneal disorders
- 1.3 Documentation that any eye disease is currently being treated with standard therapies
 - May include preservative-free artificial tears as well as lubricant or antibiotic ointments
- 1.4 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Oxervate by both a pharmacist and medical director

2. Approval Period

- 2.1 8-week treatment regimen within 6 months
 - Approval will be for the eye or eyes which were specified in the request.
- 2.2 Subsequent requests will require documentation that the patient had an initial response and then reoccurrence of neurotrophic keratitis

3. Managed Dose Limit (MDL)

- 3.1 #4 weekly packs per 28 days if treating 1 eye

CPT Codes

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HCPCS Codes

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References

1. Oxervate (cenegermin-bkbj) [prescribing information]. Boston, MA: Dompé US Inc; October 2023.
2. Deeks ED, Lamb YN. Cenegermin: A Review in Neurotrophic Keratitis. *Drugs*. 2020 Apr;80(5):489-494.
3. H Sheha, S Tighe, O Hashem, et Y Hayashida. Update On Cenegermin Eye Drops In The Treatment Of Neurotrophic Keratitis. *Clin Ophthalmol*. 2019 Oct; 13: 1973–1980.
4. Leto MG, Toro ME, Indemini PE, et al. Pediatric Use of Recombinant Human Nerve Growth Factor 20 µg/mL Eye Drops (Cenegermin) for Bilateral Neurotrophic Keratopathy in Congenital Corneal Anesthesia. *Cornea*. 2021 Feb 1;40(2):228-231.
5. Pflugfelder SC, Massaro-Giordano M, Perez VL, et al. Topical Recombinant Human Nerve Growth Factor (Cenegermin) for Neurotrophic Keratopathy: A Multicenter Randomized Vehicle-Controlled Pivotal Trial. *Ophthalmology*. 2020 Jan;127(1):14-26.
6. Sheha H, Tighe S, Hashem O, Hayashida Y. Update On Cenegermin Eye Drops In The Treatment Of Neurotrophic Keratitis. *Clin Ophthalmol*. 2019;13:1973-1980. Published 2019 Oct 7.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.