Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Oxervate (cenegermin-bkbj)

Effective: June 9, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Oxervate for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of stage 2 or 3 neurotrophic keratitis

AND

2. Prescribed by an ophthalmologist

AND

3. Documented trial and failure with **one (1)** conventional non-surgical treatment for neurotrophic keratitis (e.g., preservative-free artificial tears, gels, or ointments; discontinuation of preserved topical drops and medications that can decrease corneal sensitivity; therapeutic contact lenses)

Limitations

1. Oxervate may be authorized one time for an 8-week treatment course for each affected eye.
2. Additional treatment beyond 8-weeks will not be authorized.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Bonini S, Lambiase A, Rama P et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. Ophthalmology. 2018; 125(9):1332-1343.
2. Institute for Clinical and Economic Review (ICER). URL: https://icer -review.org/. Available from Internet. Accessed 2019 January 10. 9. Legault GL and Benfeld E. Corneal esthesiometry. 2017 December. URL: http://eyewiki.aao.org/Corneal_Esthesiometry. Available from Internet. Accessed 2019 January 23.
3. National Institute of Health and Care Excellence (NICE). Cenegermin for treating neurotrophic keratitis. 2018 July. URL: http://www.nice.org.uk. Available from Internet. Accessed 2019 January 10.
4. Oxervate (benegermin -bkbj) [prescribing information]. L'Aquila, Italy: Dompé farmaceutici S.p.A.; February 2025.
5. Sacchetti M and Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014; 8:571-9.
6. Semeraro F, Forbice E, Romano V et al. Neurotrophic keratitis. Ophthalmologica. 2014; 231(4):191-7.
7. Versura P, Ciannaccare G, Pellegrini M et al. Neurotrophic keratitis: current challenges and future prospects. Eye Brain. 2018; 10:37-45.

8. Wells JR and Michelson MA. Diagnosing and treating neurotrophic keratopathy. 2008 July/August. URL: https://www.aao.org/eyenet/article/diagnosing-treating-neurotrophickeratopathy?julyaugust-2008. Available from Internet. Accessed 2019 January.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- July 11, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24)
- June 10, 2025: Removed “The patient is at least 2 years of age” (eff 7/1/25)
- June 9, 2026: No clinical changes. Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.