Clinical Policy: Cenegermin-bkbj (Oxervate)

Reference Number: PA.CP.PMN.186
Effective Date: 01/2019
Last Review Date: 01/2024

Revision Log

Description
Cenegermin-bkbj (Oxervate™) is recombinant human nerve growth factor (rhNGF).

FDA Approved Indication(s)
Oxervate is indicated for the treatment neurotrophic keratitis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Oxervate is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neurotrophic Keratitis (must meet all)**:**

1. Diagnosis of stage 2 or 3 neurotrophic keratitis (*see Appendix D*);
2. Prescribed by or in consultation with an ophthalmologist or optometrist;
3. Age ≥ 2 years;
4. Dose does not exceed 1 vial per affected eye per day.

Approval duration: 8 weeks

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy*

A. Neurotrophic Keratitis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 vial per affected eye per day.

Approval duration: Up to a total of 8 weeks
Requests for retreatment of the same eye within one year will be reviewed on a case-by-case basis based on chart documentation of previous response to therapy and clinical rationale for re-treatment

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
rhNGF: Recombinant human nerve growth factor

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- Definitions of neurotrophic keratitis stages 1-3:
  - Stage 1: Punctate keratopathy and/or corneal epithelial hyperplasia and irregularity.
  - Stage 2: Persistent corneal epithelial defect (PED), typically oval or circular in shape, with smooth and rolled edges.
  - Stage 3: Corneal stroma and a corneal ulcer is observed. Corneal ulceration tends to progress to perforation and/or stromal melting if not promptly and properly treated.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Neurotrophic Keratitis	1 drop in the affected eye every 2 hours six times a day for 8 weeks	6 drops per affected eye per day

VI. Product Availability

Ophthalmic solution: 0.002% (20 mcg/mL)

VII. References

1. Oxervate Prescribing Information. Milan, Italy: Dompe farmaceutici S.p.A; October 2023. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761094s012s013lbl.pdf. Accessed October 24, 2023.
2. European Medicines Agency, Science Medicines Health/Assessment Report. Available at: https://www.ema.europa.eu/en/documents/assessment-report/oxervate-epar-public-assessment-report_en.pdf Updated May 18, 2017.
3. Bunya V, Woodward N, Rabiolo A, et al. Neurotrophic Keratitis. Last updated December 2021. Available at: https://eyewiki.aao.org/Neurotrophic_Keratitis. Accessed October 12, 2022.
4. 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;125:1332-1343.
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;127:14-26.

Reviews, Revisions, and Approvals	Date
1Q 2019 Policy created	01/2019
1Q 2020 annual review: Added requirement for stage 2 and 3 disease to initial approval criteria; references reviewed and updated.	01/2020
1Q 2021 annual review: no significant changes; references reviewed and updated.	01/2021
1Q 2021 annual review: references reviewed and updated.	01/2022
1Q 2023 annual review: for continued therapy added the following criteria to clarify maximum treatment duration: Member has not received ≥ 16 weeks total of Oxervate treatment per affected eye(s); clarified continued therapy approval duration limited to lifetime 2 courses of treatment *per affected eye*; references reviewed and updated.	01/2023
1Q 2024 annual review: added optometrist as an additional prescriber option; references reviewed and updated.	01/2024