Clinical Policy: Cenegermin-bkbj (Oxervate)

Reference Number: ERX.NPA.107
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

FDA Approved Indication(s)
Oxervate is a recombinant human nerve growth factor indicated for the treatment of 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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;
2. Prescribed by or in consultation with an ophthalmologist;
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Neurotrophic Keratitis (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 16 weeks (lifetime 2 courses of treatment)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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

- Definition 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 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761094s001lbl.pdf. Accessed October 4, 2021.
2. European Medicines Agency, Science Medicines Health/Assessment Report. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/004209/WC500232107.pdf. Accessed October 4, 2021.
3. Bunya V, Woodward N, Rabiolo A, et al. Neurotrophic Keratitis. Last updated December 2020. Available at: https://eyewiki.aao.org/Neurotrophic_Keratitis. Accessed October 4, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.09.18	02.19
Added requirement for stage 2 and 3 disease to initial approval criteria; references reviewed and updated.	04.16.19	08.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.30.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.26.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	10.04.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.