

Clinical Policy Title:	cenegermin-bkbj
Policy Number:	RxA.438
Drug(s) Applied:	Oxervate™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Cenegermin-bkbj (Oxervate™) is recombinant human nerve growth factor (rhNGF). It is indicated for the treatment of neurotrophic keratitis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cenegermin-bkbj (Oxervate™)	Neurotrophic keratitis	1 drop in the affected eye(s) every 2 hours six times a day for 8 weeks	6 drops per affected eye per day

Dosage Forms

- Ophthalmic solution: 0.002% (20 mcg/mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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

Commercial: 56 days

Medicaid: 56 days

II. Continued Therapy Approval

A. Neurotrophic Keratitis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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

Commercial: 112 days (lifetime 2 courses of treatment)

Medicaid: 112 days (lifetime 2 courses of treatment)

III. Appendices

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

- Contraindication(s):
 - None reported.

- Boxed Warning(s):
 - 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.

References

1. Oxervate™ Prescribing Information. Boston, MA: Dompé U.S. Inc; October 2019. Available at: https://oxervate.com/wp-content/uploads/2020/05/OXERVATE_Prescribing_Information_102019.pdf. Accessed July 9, 2021.
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. Accessed July 9, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Drug(s) Applied was updated. 2. Line of Business Policy Applies to was updated. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Commercial approval duration and 	06/25/2020	09/14/2020

<ul style="list-style-type: none"> 5. Medicaid approval duration updated. 6. Updated dosing regimen – eye to eye(s) 7. References were updated. 		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 3. References were reviewed and updated. 	<p>07/09/2021</p>	<p>9/14/2021</p>