

| | |
|--|---|
| Clinical Policy Title: | cenegermin-bkbj |
| Policy Number: | RxA.438 |
| Drug(s) Applied: | Oxervate™ |
| Original Policy Date: | 03/06/2020 |
| Last Review Date: | 12/11/2025 |
| Line of Business Policy Applies to: | All lines of business (except Medicare) |

Criteria

I. Initial Approval Criteria

A. Neurotrophic Keratitis (must meet all):

1. Diagnosis of neurotrophic keratitis.

Approval Duration

All Lines of Business (except Medicare): 56 days

II. Continued Therapy Approval

A. Neurotrophic Keratitis (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member has not received \geq 16 weeks of Oxervate treatment per affected eye.

Approval Duration

All Lines of Business (except Medicare): 112 days (lifetime 2 course of treatment)

References

1. 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 August 28, 2024.
2. Bunya V, Woodward N, Rabiolo A, et al. Neurotrophic Keratitis. Available at: https://eyewiki.aao.org/Neurotrophic_Keratitis. Accessed August 28, 2024.

| 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 | 06/25/2020 | 09/14/2020 |

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.

| | | |
|--|------------|------------|
| <p>RxAdvance..."</p> <ol style="list-style-type: none"> Commercial approval duration and Medicaid approval duration updated. References were updated. | | |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." References were reviewed and updated. | 07/09/2021 | 9/14/2021 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> References were reviewed and updated. | 03/29/2022 | 07/18/2022 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> Continued Therapy Approval Criteria, II.A.3: Updated to include new treatment duration criteria Member has not received ≥ 16 weeks total of Oxervate™ treatment per affected eye(s). References were reviewed and updated. | 04/24/2023 | 07/13/2023 |
| <p>Policy was reviewed.</p> | 10/19/2023 | 10/19/2023 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> Removed age restrictions. Removed prescriber restrictions. Removed dose restrictions. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. Removed reauthorization requirements for positive response to therapy. Updated approval duration verbiage. References were reviewed and updated. | 08/28/2024 | 9/13/2024 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> Removed the stage requirement for diagnosis. | 09/01/2025 | N/A |
| <p>Policy was reviewed.</p> | 12/11/2025 | 12/11/2025 |