MEDICAL MUTUAL®

Drug Policy

Policy:	Oxervate™ (cenegermin-bkbj ophthalmic solution)	**Annual Review Date:** **11/21/2023** **Last Revised Date:** **11/21/2023**

OVERVIEW

Oxervate, a recombinant human nerve growth factor, is indicated for the treatment of neurotrophic keratitis. Oxervate was designated as a Breakthrough Therapy and an Orphan Drug by the FDA. Oxervate works as an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (i.e., TrkA) and low-affinity (i.e. p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity.

POLICY STATEMENT

This policy involves the use of Oxervate. Prior authorization is recommended for pharmacy benefit coverage of Oxervate. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Oxervate as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Oxervate be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oxervate is recommended in those who meet the following criteria:

1. <u>Neurotrophic Keratitis</u>

Criteria. *Patient must meet the following criteria*

- **A.** Oxervate is prescribed by or in consultation with an ophthalmologist; AND
- **B.** The patient has been diagnosed with stage 2 or stage 3 Neurotrophic Keratitis as evidenced by the presence of persistent epithelial defect, PED or corneal ulcer. AND
- **C.** The patient has failed an adequate trial of at least one over-the-counter (OTC) ocular artificial tears product (e.g. Refresh Optive, Systane Ultra, Akwa Tears, etc.)

Initial Approval/ Extended Approval.

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A) *Initial Approval:* 2 months
B) *Extended Approval:* not recommended

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Oxervate has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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9. Cenegermin-bkbj. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 6 November 2021. Accessed on 18 November 2021.