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**5.90.036**

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2024
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	September 14, 2018
<b>Subject:</b>	Oxervate	<b>Page:</b>	1 of 3

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**Last Review Date:** March 8, 2024

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## Oxervate

### Description

#### Oxervate (cenegermin-bkbj)

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#### Background

Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity and low-affinity nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity (1).

#### Regulatory Status

FDA-approved indication: Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (1).

Patients should remove contact lenses before applying Oxervate and they may be reinserted 15 minutes after administration (1).

The safety and effectiveness of Oxervate in pediatric patients less than 2 years of age have not been established (1).

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#### Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

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Oxervate may be considered **medically necessary** if the conditions indicated below are met.

Oxervate may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 2 years of age and older

### Diagnosis

Patient must have the following:

Neurotrophic keratitis

**AND** the following:

1. Patient or caregiver will be counseled on proper administration technique

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## Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity** 8 kits (1 kit = 7 multiple-dose vials) per affected eye per lifetime

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## Prior – Approval *Renewal* Limits

None

### Rationale

#### Summary

Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity and low-affinity nerve growth factor receptors in the anterior

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segment of the eye to support corneal innervation and integrity. The safety and effectiveness of Oxervate in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Oxervate while maintaining optimal therapeutic outcomes.

## References

1. Oxervate [package insert]. Boston, MA: Dompe U.S. Inc.; October 2023.

## Policy History

Date	Action
September 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review
September 2020	Annual review and reference update
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review
March 2024	Annual review and reference update

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.**