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5.90.036

Section: Prescription Drugs Effective Date: April 1, 2025

Subsection: Topical Products Original Policy Date: September 14, 2018

Subject: Oxervate Page: 1 of 3

Last Review Date: March 7, 2025

Oxervate

Description

Oxervate (cenegermin-bkbj)

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).

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

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

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

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through specific high-affinity and low-affinity nerve growth factor receptors in the anterior 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.; December 2024.

Date Action	
September 2018 Addition to	PA
November 2018 Annual rev	riew
March 2019 Annual rev	riew
September 2020 Annual rev	riew and reference update
September 2021 Annual rev	riew
September 2022 Annual rev	riew
September 2023 Annual rev	riew
March 2024 Annual rev	riew and reference update
March 2025 Annual rev	riew and reference update
Keywords	

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.