Cenegermin Ophthalmic Solution

Medical Necessity Criteria

Cenegermin-bkbj Ophthalmic Solution (Oxervate™) is considered medically necessary when ALL of the following criteria are met:

- For the treatment of stage 2 (moderate) or stage 3 (severe) neurotrophic keratitis
- Prescribed by, or in consultation with, an ophthalmologist

Initial authorization is up to 2 months.

Additional courses of Cenegermin-bkbj Ophthalmic Solution (Oxervate) are considered medically necessary for continued use when the following criteria are met:

- Individual continues to meet the initial criteria
- Attestation of need for additional course of therapy based upon partial response or recurrence

Reauthorization for up to 2 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy. Cenegermin-bkbj (Oxervate) is considered experimental, investigational or unproven for ANY other use.
Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

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Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

Recommended Dosing

FDA Recommended Dosing
One drop in the affected eye(s), 6 times per day at 2-hour intervals, for eight weeks.

Drug Availability
Ophthalmic solution: cenegermin-bkbj 0.002% (20 mcg/mL) in a multiple-dose vial.

Background

OVERVIEW
Oxervate, a recombinant human nerve growth factor, is indicated for the treatment of neurotrophic keratitis.\(^1\) Oxervate was designated as a Breakthrough Therapy and an Orphan Drug by the FDA.\(^2,3\)

Disease Overview
Neurotrophic keratitis, a rare degenerative disease, is characterized by corneal epithelium breakdown, impairment of corneal healing, and development of corneal ulceration, melting, and perforation.\(^2,4,5\) Corneal epithelial cells release various neurotrophic growth factors, including nerve growth factors, which are important in maintaining the integrity and function of the ocular surface and in stimulating both epithelial and nerve fiber proliferation and survival.\(^6,7\) When corneal sensory innervation is impaired, reduction of both protective reflexes and trophic neuromodulators essential for the vitality, metabolism, and wound healing of the ocular surface tissues results. In vivo studies have shown that increasing nerve growth factor concentration after injury can accelerate healing.\(^4,7\)

Guidelines/Recommendations
Prior to the approval of Oxervate, there are no approved pharmacologic therapies for the treatment of neurotrophic keratitis.\(^2\) If neurotrophic keratitis is left untreated, the condition can progress to anatomical loss of the eye; even with treatment, loss of vision is common.\(^6\) Current treatment options are supportive and do not improve the speed of healing. Treatment should target corneal sensory innervation impairment to restore corneal integrity; treatment goals are to stop progression and reverse damage from neurotrophic keratitis. Regardless of disease severity/stage, all topical medications should be discontinued to avoid topical drug toxicity on the corneal epithelium.\(^4,5\) Additionally, preservative-free artificial tears should be used to improve lubrication. Prophylactic topical antibiotics can be considered to prevent superinfections. Associated ocular surface disease, such as exposure keratitis, dry eye, or limbal stem cell deficiency, should be treated to improve the prognosis of neurotrophic keratitis. Therapeutic contact lenses can be used to promote corneal healing.\(^7\) Surgical interventions are reserved for refractory cases.\(^4,5,7\)

References

2. Oxervate. FDA Clinical Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000TOC.cfm.
3. Oxervate. FDA Pharmacology Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000TOC.cfm.