Washington State Health Care Authority

Ophthalmic Agents: Cenegermin-bkbj (Oxervate)

Medical policy no. 86.77.00.AA-1 Effective Date: 4/1/2024

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Cenegermin-bkbj (Oxervate)	**Cenegermin-bkbj (Oxervate)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis.

Clinical policy:

Clinical Criteria	
Neurotrophic Keratitis cenegermin-bkbj (Oxervate)	Cenegermin-bkbj (Oxervate) may be approved when all the following criteria are met: 1. A diagnosis of neurotrophic keratitis (NK); **AND** 2. Prescribed by, or in consultation with a specialist (i.e., ophthalmologist, optometrist); **AND** 3. Antibiotic drops in combination with preservative-free artificial tears has been ineffective, contraindicated, or not tolerated (minimum 14-day trial); **AND** 4. Patient has NOT received prior therapy with cenegermin-bkbj (Oxervate), in the requested eye, in their lifetime; **AND** 5. One of the following categories apply (a or b): a. Patient has Stage 3 (corneal ulceration, corneal perforation, or corneal stromal melting) disease; **OR** b. Patient has Stage 2 (persistent epithelial defect); **AND** i. Therapeutic contact lens (scleral lens) has been ineffective, contraindicated, or are not tolerated If ALL criteria are met, the request will be authorized for **eight weeks.**
	Criteria (Reauthorization)
	Not eligible for reauthorization.

	Treatment beyond the initial eight-week duration is considered experimental and investigational.

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
Oxervate	Neurotrophic Keratitis	1 drop into affected eye(s) 6 times daily for 8 weeks	• 0.002% (20 mcg/mL) vial: 56 mL per affected eye, 112 mL per lifetime

Background:

Neurotrophic keratitis (NK) is a rare, degenerative disease of the cornea caused by damage to the trigeminal nerve, which results in reduction or loss of corneal sensitivity, epithelium breakdown, decreased corneal healing, ulceration, melting, and perforation. The goal of therapy is to prevent progression of corneal damage and promote healing of the corneal epithelium. Per John Hopkins Medicine, An Evidence-based Approach to the Diagnosis and Treatment of Neurotrophic Keratopathy, treatment of NK is based on disease severity; however, use of preservative-free artificial tears may help improve the corneal surface at all stages of disease severity. Topical antibiotic eye drops are recommended in eyes with NK at stages 2 and 3 to prevent infection. Nonpharmacological treatments for NK include therapeutic corneal or scleral contact lenses in the event of persistent epithelial defects (PED) to promote corneal epithelial healing. Surgical treatments are reserved for refractory cases.

Cenegermin-bkbj (Oxervate) is a recombinant human eye growth factor ophthalmic solution indicated for the treatment of neurotrophic keratitis. Cenegermin-bkbj (Oxervate) was studied in two 8-week, phase II multi-center, randomized, double blind, placebo controlled clinical trials (Study NGF0212 (REPARO) and Study NGF0214) in adult patients with Stage 2 or Stage 3 NK who were refractory to 1 or more conventional nonsurgical treatments. Retreatment following recurrence was not assessed in either study. Efficacy of cenegermin-bkbj (Oxervate) beyond a single 8-week course of treatment or repeat treatment has not been evaluated

References

1. Oxervate [Prescribing Information]. Boston, MA: Dompé US, Inc. October 2019.
2. Bonini S, Lambiase A, Rama P, et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neutrophic keratitis. Opthalmology. 2018;125(9):1332-1343.
3. Shaheen B, Bakir M, Jain S. Corneal nerves in health and disease. Surv Opthalmol. 2014;59(3):263-285.
4. Mantelli F, Nardella C, Tiberi E, et al. Congenital corneal anesthesia and neurotrophic keratitis: diagnosis and management. Biomed Res Int. 2015;2015:805876. Epub Sept. 16, 2015.
5. Semeraro F, Forbice E, Romano V, et al. Neurotrophic keratitis. Opthalmologica. 2014;231(4):191-197.
6. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Opthalmol. 2014;8:571-579.
7. An Evidence based Approach to the Diagnosis and Treatment of Neurotrophic Keratopathy. CME monograph. Johns Hopkins School of Medicine. March 2020. Available at: https://hopkinscme.cloud-cme.com/assets/hopkinscme/Presentations/28879/28879.pdf

History

Approved Date	Effective Date	Version	Action and Summary of Changes
10/18/2023	04/01/2024	86.77.00.AA-1	Approved by DUR Board -New policy