VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Oxervate Prior Authorization Policy
- Oxervate™ (cenegermin-bkbj ophthalmic solution – Dompé)

REVIEW DATE: 08/04/2021

OVERVIEW

Oxervate, a recombinant human nerve growth factor, is indicated for the treatment of **neurotrophic keratitis**.[1]

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] 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.[5,6] 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.[3,6]

Guidelines/Recommendations

Prior to the approval of Oxervate, there were 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.[5] 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.[3,4] 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.[6] Surgical interventions are reserved for refractory cases.[3,4.6]

Duration of Treatment

The recommended dosing regimen is one drop six times a day (at 2 hour intervals) for 8 weeks.[1] In one of the pivotal studies, five patients who experienced a recurrence of neurotrophic keratitis after an 8-week course of Oxervate were re-treated with another 8 weeks of Oxervate.[7] Four of these patients achieved corneal healing, which was maintained through the end of the follow-up period.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Oxervate. All approvals are provided for the duration noted below. 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, approval requires Oxervate to be prescribed by a physician/specialist who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Neurotrophic Keratitis.** Approve if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 8 weeks if Oxervate is prescribed by an ophthalmologist or optometrist; OR
   - **B)** Patient Who Has Previously Received Oxervate. Approve for 8 weeks if the patient meets the following criteria (i, ii, and iii):
     - **i.** Patient has previously received ≤ 8 weeks of treatment per affected eye(s); AND
     - **ii.** Patient has a recurrence of neurotrophic keratitis; AND
     - **iii.** The medication is prescribed by an ophthalmologist or optometrist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Oxervate is not recommended in the following situations:

1. **Treatment Duration of > 16 Weeks Per Affected Eye(s).** Available data supports use of Oxervate for up to 16 weeks.[2,7]

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

REFERENCES

1. Oxervate™ ophthalmic solution [prescribing information]. Boston, MA: Dompé US.; October 2019.
2. Oxervate. FDA Clinical Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000TOC.cfm. Accessed on August 3, 2021.
3. Mastropasqua L, Massaro-Giordano G, Nubile M, Sacchetti M. Understanding the pathogenesis of neurotrophic keratitis: the role of the corneal nerve. *J Cell Physiol*. 2017;232:717-724.
4. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthamol*. 2018;8:571-579.
5. Dua HS, Said DG, Messmer EM, et al. Neurotrophic keratopathy. *Progress in Retinal and Eye Research*. 2018;16:107-131.
6. Vesura P, Giannaccare G, Pellegrini M, et al. Neurotrophic keratitis: current challenges and future prospects. *Eye and Brain*. 2018;10:37-45.
7. Pflugfelder SC, Massaro-Giordano M, Perez VL, et al. Topical recombinant human nerve growth factor (cenegermin) for neurotrophic keratopathy. A multicenter randomized vehicle-controlled pivotal trial. *Ophthalmology*. 2020;127:127:14-26.