ALASKA MEDICAID Prior Authorization Criteria

OxervateTM (cenegermin-bkbj)

FDA INDICATIONS AND USAGE^{1,3}

OxervateTM (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). NK is a degenerative disease that decreases corneal sensitivity and healing, leaving the cornea to be more susceptible to injury and decreased reflex tearing.

APPROVAL CRITERIA^{1,2,3}

- 1. Patient is 2 years of age or older **AND**;
- 2. Patient has a documented diagnosis of stage 2 (persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in one or both eyes **AND**;
- 3. Is being prescribed by or in consultation with an ophthalmologist or optometrist **AND**;
- 4. The patient has evidence of decreased corneal sensitivity in at least one eye **AND**;
- 5. The patient has a documented treatment with one or more conventional non-surgical treatments for neurotrophic keratitis.

DENIAL CRITERIA

1. Failure to meet approval criteria.

CAUTIONS¹

- The most common adverse reactions are eye pain, ocular hyperemia, eye inflammation and increased lacrimation.
- Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.
- Patients should follow proper administration and storage procedures outlined in the package insert.

DURATION OF APPROVAL

- Initial Approval: up to 8 weeks (treatment duration not to exceed 8 weeks)
- Retreatment, lost or stolen, or spilled medication should not be authorized.

OUANTITY LIMIT

• Up to maximum of 8 kits per affected eye (1 kit contains 7 multiple-dose vials)

REFERENCES / FOOTNOTES:

OxervateTM Criteria Version: 1

Original: 07/06/2020 Approval: 09/18/2020 Effective: 11/16/2020

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- 1. Oxervate[™] [prescribing information]. Boston, MA: Dompe U.S. Inc.; October 2019.
- 2. Sacchetti, M., Lambiase, A. Diagnosis and management of neurotrophic keratitis. Clinical Ophthalmology 2014;8: 571-9.
- 3. Evaluation of Safety and Efficacy of rhNGF in Patients With Stage 2 and 3 Neurotrophic Keratitis. Full Text View ClinicalTrials.gov. (2019). Retrieved from https://clinicaltrials.gov/ct2/show/NCT01756456

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