Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 2019

Prior Authorization: Oxervate

Products Affected: Oxervate (cenegermin-bkbj) 0.002% ophthalmic solution

Medication Description:
Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (i.e., TrkA) and low-affinity (i.e. p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity. Treatment with recombinant growth factor restores the function of the injured neurons, and subsequently, corneal homeostasis.

Covered Uses: Neurotrophic keratitis

Exclusion Criteria: N/A

Required Medical Information:
1. Documented diagnosis
2. Previous therapies tried

Age Restrictions: 2 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an ophthalmologist

Coverage Duration: 8 weeks*
*Note: Reauthorization will not be approved as there have been no studies to document the efficacy of treatment beyond a single 8-week course.

Other Criteria:
1. **Neurotrophic keratitis**. Approve if patient meets the following criteria:
    a. Patient has a documented diagnosis of stage 2 [recurrent/persistent epithelial defect (PED)] or stage 3 (corneal ulcer) neurotrophic keratitis; **AND**
    b. Patient is 2 years of age or older; **AND**
    c. Oxervate is prescribed by, or in consultation with, an ophthalmologist; **AND**
    d. Patient has tried and failed treatment with one or more conventional non-surgical treatment for neurotrophic keratitis:
        i. Ophthalmic lubricants (preservative-free artificial tears, gel, or ointment); **OR**
        ii. Therapeutic contact lenses
    e. The request specifies the affected eye(s) intended for treatment

*Note: Reauthorization will not be approved as there have been no studies to document the efficacy of treatment beyond a single 8-week course.

References:

1. Oxervate [prescribing information]. Boston, MA: Dompé U.S. Inc.; April 2019.
2. Food & Drug Administration. FDA approves first drug for neurotrophic keratitis, a rare eye disease. August 2018. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618047.htm. Accessed March 28, 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	04/24/2019