

Oxervate (cenegermin-bkbj)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	8 weeks; Limit of two 8-week courses of treatment total

Medications	Quantity Limit
Oxervate (cenegermin-bkbj) vials	May be subject to quantity limit

APPROVAL CRITERIA

Requests for an initial 8-week course or up to one additional 8-week course of Oxervate (cenegermin-bkbj) may be approved if the following criteria are met (Bonini 2018, Pflugfelder 2020):

- I. Documentation is provided that individual has a diagnosis of stage 2 or stage 3 neurotrophic keratitis in one or both eyes, as shown by the presence of one of the following:

- A. Persistent epithelial defect(s); **OR**
- B. Corneal ulcer(s);

AND

- II. Individual has evidence of decreased corneal sensitivity in at least one corneal quadrant;

AND

- III. Individual has failed one or more conventional non-surgical treatments for neurotrophic keratitis such as artificial tears, gels, or ointments.

Key References:

1. Bonini, S; Lambiase, A; Rama, P; et al; Phase II Randomized, Double-Masked, Vehicle-Controlled Trial of Recombinant Human Nerve Growth Factor for Neurotrophic Keratitis. *Ophthalmology* 2018; 125: 1332-1243.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 1, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. 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;127:14-26.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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