cenegermin-bkbi (Oxervate™)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO013

Description

Cenegermin-bkbj (Oxervate) is a recombinant human eye growth factor ophthalmic solution indicated for the treatment of neurotrophic keratitis.

Length of Authorization

- Initial: Eight weeks
- Renewal: Not approvable

Quantity limits

cenegermin-bkbj (Oxervate)	Indication	Quantity Limit	DDID
0.002% (20 mcg/mL) vial	Neurotrophic keratitis	56mL per lifetime	204913

Initial Evaluation

I. Cenegermin-bkbj (Oxervate) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by or in consultation with an ophthalmologist; **AND**
   B. A diagnosis of Neurotropic Keratitis; **AND**
   C. Documentation of cause not due to infective or autoimmune keratitis; **AND**
   D. Lack of active ocular infection (bacterial, viral, fungal, or protozoal); **AND**
   E. Lack of current severe blepharitis and/or severe meibomian gland disease; **AND**
   F. Stage 2 (persistent epithelial defect) or Stage 3 (corneal ulceration) disease; **AND**
   G. History of use of all of the following:
      1. Antibiotic drops in combination with preservative-free artificial tears; **AND**
      2. Topical collagenase inhibitor (e.g. N-acetylcysteine, tetracycline, medroxyprogesterone) ; **AND**
      3. Therapeutic contact lens

II. Cenegermin-bkbj (Oxervate) is considered investigational when used for all other conditions, including but not limited to:
   A. Treatment duration longer than 8 weeks

Renewal Evaluation

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

Supporting Evidence

I. Clinical trials was studied in two 8-week, phase II multi-center, randomized, double blind, placebo controlled clinical trials with specific inclusion and exclusion protocol to which policy aligns.
II. Standard of care therapies include history of use of antibiotic eye drops in combination with artificial tears, topical collagenase inhibitors and therapeutic contact lens.
III. Lack of studies to demonstrating efficacy beyond a single 8 weeks course of treatment.

Investigational or Not Medically Necessary Uses

I. Neurotrophic Keratitis
   A. Treatment beyond the initial 8 week duration is considered experimental and investigational due to lack of studies to demonstrating efficacy beyond a single eight weeks course of treatment.

References

1. Oxervate [Prescribing Information]. Boston, MA: Dompé US, Inc. August 2018.
2. FDA approves first drug for neurotrophic keratitis, a rare eye disease [Press Release]. U.S. Food and Drug Administration. Accessed October 23, 2018. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm618047.htm.
3. Dompé receives FDA approval of Oxervate, the first drug for neurotrophic keratitis [Press Release]. Eyewire News. August 23, 2018. Available at: https://eyewire.news/articles/dompe-receives-fda-approval-of-oxervate-a-first-in-class-treatment-of-neurotrophic-keratitis/.
4. 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.
5. Shaheen B, Bakir M, Jain S. Corneal nerves in health and disease. *Surv Opthalmol.* 2014;59(3):263-285.
6. Tarsorrhaphy. American Academy of Ophthalmology (AAO). Accessed October 30, 2018. Available at: https://www.aao.org/bcscsnippetdetail.aspx?id=3c2b27d8-c930-4a31-8036-9ce3dcebaf61.
7. Brennan K. Thicker than water: autologous serum. *Review of Opthalmology.* Published November 5, 2016. Accessed October 30, 2018. Available at: https://www.reviewofophthalmology.com/article/thicker-than-water-autologous-serum.
8. 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.
9. Semeraro F, Forbice E, Romano V, et al. Neurotrophic keratitis. *Opthalmologica*. 2014;231(4):191-197.
10. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Opthalmol.* 2014;8:571-579.
11. Voelker R. New drug treats rare, debilitating neurotrophic keratitis. *JAMA*. 2018;320(13):1309.
12. Lambiase A, Sacchetti M, Bonini S. Nerve growth factor therapy for corneal disease. *Curr Opin Opthalmol.* 2012;23(4):296-302.
13. Versura R, Giannaccare G, Pellegrini M, et al. Neurotrophic keratitis: current challenges and future prospects. *Eye Brain.* 2018;10:37-45.

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Policy Implementation/Update:

Date Created	January 2019
Date Effective	February 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date