

Oxervate® (cenegermin-bkbj)
Effective 01/01/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Oxervate (cenegermin-bkbj) is a recombinant form of human nerve growth factor (rhNGF) indicated for the treatment of stage 2 and 3 neurotrophic keratitis (NK) in adult and pediatric patients two years of age or older.

No PA	Drugs that require PA
artificial tears *	Oxervate® (cenegermin-bkbj)

*This is a generic over-the-counter (OTC) medication

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization will be granted when all the following criteria has been met, and documentation has been submitted:

Neurotrophic keratitis (Neurotrophic keratoconjunctivitis)

1. Diagnosis of stage 2 or 3 neurotrophic keratitis
2. Member is ≥ 2 years of age
3. Prescriber is a specialist (e.g. ophthalmologist) or consult notes from specialist are provided

Continuation of Therapy



Data to support repeat dosing of Oxervate® (cenegermin-bkbj) is currently limited to five patients from one study.⁹ Further investigation into re-treatment following disease recurrence is needed.¹⁰ If a request for reauthorization is received, these are reviewed on a case-by-case basis.

Limitations

1. Approvals will be authorized for 2 months.

References

1. Oxervate® (cenegermin-bkbj) [package insert]. Milan (IT): Dompé farmaceutici S.p.A.; 2019 Oct.
2. Dompé receives FDA approval cenegermin eye drops, first-in class recombinant human nerve growth factor with potential to completely heal rare neurotrophic keratitis. Milan (IT): Dompé farmaceutici S.p.A.; 2018 [cited 2019 Jan 18]. Available from: http://www.dompe.com/news-en/833_dompe-receives-fda-approval-cenegermin-eye-drops-first-in-class.html.
3. StatPearls. Neurotrophic Keratitis [webpage on the internet]. Treasure Island (FL); 2020 [cited 2021 Jan 22]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK431106/>.
4. American Academy of Ophthalmology. Diagnosing and Treating Neurotrophic Keratopathy [webpage on the internet]. San Francisco (CA): American Academy of Ophthalmology; 2008 [cited 2021 Jan 22]. Available from: <https://www.aao.org/eyenet/article/diagnosing-treating-neurotrophic-keratopathy?julyaugust-2008>.
5. Bonini S, Rama P, Olzi D, Lambiase A. Neurotrophic keratitis. *Eye (Lond)*. 2003;17:989-995.
6. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol*. 2014;8:571- 579.
7. Bonini S, Lambiase A, Rama P, Sinigaglia F, Allegretti M, Chao W, et al. Phase II Randomized, Double- Masked Vehicle-Controlled Trial of Recombinant Human Nerve Growth Factor for Neurotrophic Keratitis. *Ophthalmology*. 2018 Sep;125(9):1332-1343.
8. Cision: PR Newswire. Dompe announces first treatment with Oxervate eye drops (cenegermin-bkbj), for neurotrophic keratitis (NK) [webpage on the internet]. San Bruno (CA): Cision: PR Newswire. 2019 Jan 3 [cited 2021 Jan 22]. Available from: <https://www.prnewswire.com/news-releases/dompe-announces-first-treatment-with-oxervate-eye-drops-cenegermin-bkbj-for-neurotrophic-keratitis-nk-300772376.html>.
9. Plugfelder SC, Massaro-Giordano M, Perez VL, Hamrah P, Deng SX, Espandar L, et al. Topical Recombinant Human Nerve Growth Factor (Cenegermin) for Neurotrophic Keratopathy: A Multicenter Randomized Vehicle- Controlled Pivotal Trial. *Ophthalmology*. 2020 Jan;127(1):14-26.
10. Deeks ED, Lamb YN. Cenegermin: A Review in Neurotrophic Keratitis. *Drugs*. 2020 Apr;80(5):489-494.

Review History

09/21/2022 – Created for Sept P&T; matched MH UPPL. Effective 01/01/2023

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