



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Oxervate Clinical Edit
<b>First Implementation Date:</b>	October 17, 2019
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Oxervate™ (cenegermin-bkbj)

**Why Issue Selected:** On August 22, 2018, the FDA approved Oxervate™ (cenegermin-bkbj), representing the first application of a human nerve growth factor as a drug or treatment and the first topical biologic medication approved in ophthalmology. Oxervate is indicated for treatment of neurotrophic keratitis (NK) in adults and children 2 years of age and older. NK is a degenerative disease of the cornea caused by damage of the trigeminal nerve, which results in impairment of corneal sensitivity, spontaneous corneal epithelium breakdown, poor corneal healing, and development of corneal ulceration, melting, and perforation. The loss of corneal sensation impairs corneal health causing progressive damage to the top layer of the cornea, including corneal thinning, ulceration, and perforation in severe cases. The prevalence of neurotrophic keratitis has been estimated to be less than five in 10,000 individuals. NK can be divided into 3 stages, with current treatments based upon staging. Stage 1 is characterized by mild, nonspecific signs and symptoms and treated with preservative-free artificial tears and ointments as well as consideration of punctal occlusion. Stage 2 involves a nonhealing corneal epithelial defect treated with prophylactic antibiotic drops in addition to preservative free tears; a lateral tarsorrhaphy, injection of botulinum A toxin, or amniotic membrane transplantation may also be recommended. Stage 3 is characterized by stromal melting leading to perforation; the patient is often asymptomatic at this stage due to decreased corneal sensation. Stromal melting may be treated with topical collagenase inhibitors such as N-acetylcysteine, tetracycline or medroxyprogesterone. Oxervate is a recombinant human nerve growth factor that binds to specific high-affinity (i.e., TrkA) and low-affinity (i.e., p75NTR) receptors in the anterior segment of the eye to support corneal innervation and integrity in patients with NK. Due to Oxervate's highly specific indication and cost, MO HealthNet will impose criteria to ensure appropriate utilization.

### Program-Specific Information:

Date Range FFS 4-1-2020 to 3-31-2021			
Drug	Claims	Spend	Avg Spend per Claim
OXERVATE 0.002% EYE DROP	7	\$169,130.85	\$24,161.55

**Type of Criteria:**
 Increased risk of ADE
 Preferred Drug List
 Appropriate Indications
 Clinical Edit

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Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Oxervate™ (cenegermin-bkbj)
- Age range: All appropriate MO HealthNet participants aged 2 years and older

## Approval Criteria

### Initial therapy:

- Participant aged 2 years or older **AND**
- Diagnosis of stage 2 or stage 3 neurotrophic keratitis (NK) **AND**
- For stage 2 NK: documented trial of preservative-free artificial tears and ointment **AND** prophylactic antibiotic drops **OR**
- For stage 3 NK: documented trial of N-acetylcysteine, tetracycline, or medroxyprogesterone

### Continuation of therapy:

- Initial approval of prior authorization is 8 weeks
- Demonstration of previous beneficial results in therapy required for renewal of prior authorization

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:

  

Progress Notes:

  

MedWatch Form:

Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

8 weeks

## References

- OXERVATE™ (cenegermin-bkbj) ophthalmic solution [package insert]. Boston, MA: Dompé U.S. Inc.; October 2019.
- IPD Analytics. Rx Insights New Drug Approval Review: Oxervate. September 2018.
- IPD Analytics. Ophthalmics: Rare Ophthalmic Conditions. Accessed May 6, 2021.

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