

SmartPA Criteria Proposal

Drug/Drug Class:	Oxervate Clinical Edit
First Implementation Date:	October 17, 2019
Proposed Date:	March 17, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<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 high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Oxervate.

Program-Specific Information:

Date Range FFS 1-1-21 to 12-31-21			
Drug	Claims	Spend	Avg Spend per Claim
OXERVATE 0.002% EYE DROP	7	\$169,125.95	\$24,160.85

Type of Criteria: Increased risk of ADE Preferred Drug List

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Appropriate Indications

Clinical Edit

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:
MedWatch Form:

Progress Notes:
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 February 2, 2022.

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