SmartPA Criteria Proposal

Drug/Drug Class:	Oxervate Clinical Edit
First Implementation Date:	October 17, 2019
Proposed Date:	April 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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. Neurotrophic keratitis (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. The active ingredient in Oxervate, cenegermin, is a structurally identical to endogenously produced nerve growth factor.

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 1-1-22 to 12-31-22			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
OXERVATE 0.002% EYE DROP	8	$202,754.40	$25,344.30

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List**
☐ **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:		Progress Notes:	X
MedWatch Form:		Other:	X

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 January 20, 2023.