SmartPA Criteria Proposal

Drug/Drug Class:	Oxervate™ Clinical Edit
First Implementation Date:	October 17, 2019
Proposed Date:	June 18, 2020
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) ophthalmic solution

Why Issue Selected: On August 22, 2018, the FDA approved Oxervate™ (cenegermin-bkbj), representing the first application of a human nerve growth factor as 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 4-1-2019 to 3-31-2020			
Drug	**Claims**	**Cost per vial**	**Cost per 8 week treatment of 1 eye (56 vials)**
OXERVATE 0.002% EYE DROP	0	$1,725.14 MAC	$96,607.84 MAC

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) ophthalmic solution
- 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 no approval crieria are 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.