DRUG DETERMINATION POLICY

Title: DDP-49 Oxervate

Effective Date: 03/09/2021

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Oxervate, a recombinant human nerve growth factor (NGF), is a specialty drug indicated for the treatment of neurotrophic keratitis. Neurotrophic keratitis is a rare degenerative corneal disease that impairs corneal sensation. Loss of corneal sensitivity can cause epithelial thinning, ulceration, and perforation if left untreated. These criteria were developed and implemented to ensure appropriate use for the intended diagnosis.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Neurotrophic keratitis [must meet all listed below]

   1. Age: at least two years.

   2. Prescriber: ophthalmologist, optometrist, corneal specialist, neurologist.

   3. Diagnosis and severity [must meet one listed below]:

      a. Stage 2 neurotrophic keratitis (refer to Appendix II).

      b. Stage 3 neurotrophic keratitis (refer to Appendix II).

   4. Other therapies: contraindication, inadequate response after four months or significant adverse effects to all pertinent categories listed below:

a. For stage 2 neurotrophic keratitis: preservative-free artificial tears/ointments and antibiotic eye drops.

b. For stage 3 neurotrophic keratitis: N-acetylcysteine, tetracycline, or medroxyprogesterone.

5. Dosage and administration.

   a. Dosage regimen: instill one drop into affected eye(s) every two hours for six doses daily.

   b. Documented patient education regarding administration with contact lenses and other topical ophthalmic products such as eye ointment, gel or other viscous eye drops.

   c. Member must agree to case management by the Health Plan.

6. Approval.

   a. Initial: eight weeks.

   b. Re-approval: not indicated.

4.0 Coding:

CODES AFFECTED				
Code	**Brand**	**Generic**	**Billing (1u)**	**Prior Approval Required**
N/A	Oxervate	cenegermin-bkbj	0.002% (20 mcg/mL)	Y

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Oxervate accessed December 2020.
2. Pflugfelder, S., Massaro-Giordano, M., Perez, V., Hamrah, et. al. Topical Recombinant Human Nerve Growth Factor (Cenegermin) for Neurotrophic Keratopathy. Ophthalmology. 2020; 127(1):14-26.
3. Dua HS, Said DG, Messmer EM, et al. Neurotrophic keratopathy. Prog Retin Eye Resin. 2018; 66:107-131.
4. Oxervate [prescribing information]. Boston, MA: Dompé U.S. Inc.; August 2018.

6.0 Appendices:

See page 3.

7.0 Revision History:

Original Effective Date: 03/09/2021

Next Review Date: 03/09/2022

Revision Date	Reason for Revision

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Oxervate (cenegermin-bkbj)	• Ophthalmic: eye pain (16%), corneal deposits (1-10%), lacrimation (1-10%), ocular hyperemia (1-10%), ophthalmic inflammation (1-10%) • Central nervous system: foreign body sensation (1-10%)	• Adverse events such as severe eye pain • Corneal examination every 8 weeks	N/A

Appendix II: Neurotrophic Keratitis Staging

Stages of Neurotrophic Keratitis	Signs and Symptoms
Stage 1	• Dry and opaque corneal epithelium • Superficial punctuate keratopathy • Corneal edema • Stromal scarring • Corneal neovascularization
Stage 2	• Persistent epithelial defect (PED) • Stromal swelling • Loose corneal epithelium
Stage 3	• Corneal ulcer • Corneal perforation • Stromal lysis/melting