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Oxervate (cenegermin-bkbj)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

POLICY

Criteria for Initial Approval

A.) Neurotrophic keratitis

Authorization of 8 weeks may be granted for treatment of Stage 2 and Stage 3 neurotrophic keratitis when all of the following criteria are met:

- 1.) The patient must experience persistent epithelial defects (PED) or corneal ulceration of at least 2 weeks duration refractory to one or more conventional non-surgical treatments (e.g., preservative free artificial tears).
- 2.) Evidence of decreased corneal sensitivity (less than or equal to 4 cm using the Cochet-Bonnet aesthesiometer) within the area of the PED or corneal ulcer and outside of the area of the defect in at least one corneal quadrant.
- 3.) The patient has not received a previous 8 week course of Oxervate in the affected eye.

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

8 kits (1 kit = 7 x 1 mL multiple-dose vials) per affected eye per lifetime

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Oxervate [package insert]. Boston, MA: Dompe U.S. Inc.; October 2019.

POLICY HISTORY

Policy #: 05.02.73

Original Effective Date: June 12, 2019

Reviewed: October 2021

Revised: April 2020

Current Effective Date: June 29, 2020