Original Effective Date: 01/2019
Current Effective Date: 12/21/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C16015-A

Oxervate (cenegermin)

PRODUCTS AFFECTED

Oxervate (cenegermin-bkbj)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neurotrophic keratitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. NEUROTROPHIC KERATITIS:
1. Documented diagnosis of stage 2 (persistent epithelial defect, PED) or stage 3 (corneal ulcer) neurotrophic keratitis (NK)

AND

2. Documentation member has failed treatment with one or more conventional treatments for NK such as preservative-free ophthalmic lubricants (artificial tears, gel, or ointment)

CONTINUATION OF THERAPY:
NA, Retreatment courses will not be approved as there have been no studies to document the efficacy of treatment beyond a single 8-week course

DURATION OF APPROVAL:
Initial authorization: 8 weeks, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by a board-certified optometrist or ophthalmologist.

AGE RESTRICTIONS:
2 years of age and older

QUANTITY:
6 drops per affected eye per day for eight weeks

Maximum Quantity Limits – 8 kits (1 kit = 7 multiple-dose vials [1 vial per day of the week]) per affected eye per lifetime

PLACE OF ADMINISTRATION:
The recommendation is that ophthalmic instillation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Ophthalmic instillation

DRUG CLASS:
Ophthalmic Nerve Growth Factors

FDA-APPROVED USES:
Indicated for the treatment of neurotrophic keratitis

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Definitions of neurotrophic keratitis stages 1-3:

- Stage 1: Punctate keratopathy and/or corneal epithelial hyperplasia and irregularity.
- Stage 2: Persistent corneal epithelial defect (PED), typically oval or circular in shape,
- with smooth and rolled edges.
- Stage 3: Corneal stroma and a corneal ulcer is observed. Corneal ulceration tends to progress to perforation and/or stromal melting if not promptly and properly treated.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity and low-affinity nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Oxervate (cenegermin-bkbj) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Oxervate (cenegermin-bkbj) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
If a dose is missed, treatment should be continued as normal, at the next scheduled administration. Weekly kits must be refrigerated by the patient and can be stored for up to 14 days in the fridge in the original carton. Oxervate is stored in the freezer at the pharmacy.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Oxervate SOLN 0.002% weekly carton containing 7 multiple dose vials (1 vial per day of the week)

REFERENCES

1. Oxervate (cenegermin-bkbj) [prescribing information]. Boston, MA: Dompé US Inc; October 2019.
2. Evaluation of Safety and Efficacy of rhNGF in Member s with Stage 2 and 3 Neurotrophic Keratitis. - Full Text View - ClinicalTrials.gov. (2019). Retrieved from https://clinicaltrials.gov/ct2/show/NCT01756456

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Duration of Approval Quantity FDA-Approved Uses Other Special Considerations Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Contraindications/Exclusions/Discontinuation Other Special Considerations	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file