Pharmacy Medical Necessity Guidelines: Oxervate™ (cenegermin-bkbj)

Effective: June 9, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Oxervate (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

COVERAGE GUIDELINES

The plan may authorize coverage of Oxervate (cenegermin-bkbj) for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of stage 2 or 3 neurotrophic keratitis

AND

2. Prescribed by an ophthalmologist

AND

3. Documentation of treatment failure with one (1) conventional non-surgical treatment for neurotrophic keratitis (e.g., preservative-free artificial tears, gels or ointments; discontinuation of preserved topical drops and medications that can decrease corneal sensitivity; therapeutic contact lenses)

LIMITATIONS

- Oxervate may be authorized one time for an 8-week treatment course for each affected eye.
- Additional treatment beyond 8-weeks will not be authorized.

CODES

None

REFERENCES

1. Bonini S, Lambiase A, Rama P et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. Ophthalmology. 2018; 125(9):1332-1343.
2. Oxervate (benegermin -bkbj) [prescribing information]. L'Aquila, Italy: Dompé farmaceutici S.p.A.; October 2023.
3. Sacchetti M and Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014; 8:571-9.
4. Semeraro F, Forbice E, Romano V et al. Neurotrophic keratitis. Ophthalmologica. 2014; 231(4):191-7.
5. Versura P, Ciannaccare G, Pellegrini M et al. Neurotrophic keratitis: current challenges and future prospects. Eye Brain. 2018; 10:37-45.
6. Wells JR and Michelson MA. Diagnosing and treating neurotrophic keratopathy. 2008 July/August. URL: https://www.aao.org/eyenet/article/diagnosing-treating-neurotrophic-keratopathy?julyaugust-2008. Available from Internet. Accessed 2019 January 11.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- July 11, 2023: No changes.
- June 11, 2024: No changes
- June 10, 2025: Removed "The Member is 2 years of age or older" (eff 7/1/25)
- June 9, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services