

[Office letterhead]

[Date]

[Contact name of medical director or other payor representative]

[Contact title]

[Name of health insurance company]

[Address]

Re: Letter of Medical Necessity for OXERVATE (cenegermin-bkbj) ophthalmic solution, per treatment course

Patient: [Patient Name]

Group/Policy Number: [Number]

Date(s) of Service: [Dates]

Diagnosis: [H16.23X Neurotrophic keratoconjunctivitis]

Dear [Insert contact name or department],

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with OXERVATE® (cenegermin-bkbj). This patient will be treated for neurotrophic keratitis with OXERVATE, which is indicated for the treatment of neurotrophic keratitis.¹ This letter serves to document that [PATIENT] needs OXERVATE and that OXERVATE is medically necessary for them as administered. On behalf of the patient, I am requesting approval for use and subsequent payment for treatment.

Medical History and Diagnosis

[PATIENT NAME] is [a/an] [AGE]-year-old [MALE/FEMALE] diagnosed with neurotrophic keratitis. [PATIENT NAME] has been in my care since [DATE]. As a result of neurotrophic keratitis, my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT NAME] has tried [PREVIOUS TREATMENTS] and [OUTCOMES]. The attached medical records document [PATIENT NAME]'s clinical condition and the medical necessity for treatments with OXERVATE.

Based on the clinical evidence and the patient's documented response to prior therapies, I respectfully request approval for OXERVATE as a medically necessary treatment. OXERVATE is the only FDA-approved treatment indicated for the treatment of neurotrophic keratitis (Stages 1-3).^{1,2} The plan of treatment is to start the patient on OXERVATE. Instillation of one drop of OXERVATE in the affected eye(s) is planned 6 times daily at 2-hour intervals, starting on [DATE], and will be continued for a total of 8 weeks.¹

Please consider coverage of OXERVATE on [PATIENT NAME]'s behalf and approve use and subsequent payment for OXERVATE as planned. Please refer to the enclosed Prescribing Information for OXERVATE. If you have any further questions, please call me at [PHYSICIAN TELEPHONE NUMBER].

Thank you for your prompt attention to this matter.

Sincerely,

[PHYSICIAN NAME], [DEGREE INITIALS]
[PROVIDER IDENTIFICATION NUMBER]

Enclosures:

- Chart notes and test results
- Supporting medical studies
- Patient narrative
- Prescribing Information: <https://oxervate.com/prescribing-information>
- FDA approval letter: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&AppNo=761094>

References:

1. OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. San Mateo, CA: Dompé U.S. Inc.; 2024.
2. FDA approves first drug for neurotrophic keratitis, a rare eye disease. U.S. Food and Drug Administration; August 22, 2018. Accessed December 3, 2024.