

Composing an Appeal Letter for patients who have been prescribed OXERVATE® (cenegermin-bkjb) ophthalmic solution 0.002% (20 mcg/mL)

If your patient's insurance plan denies coverage for OXERVATE® (cenegermin-bkjb) ophthalmic solution 0.002% (20 mcg/mL), your patient has the right to submit an appeal. You can support your patient's appeal by providing a letter with additional details about the clinical, decision-making rationale for your prescription of OXERVATE for this particular patient.

Writing a letter in support of an appeal?

1. If your patient's coverage is denied, **the insurance plan will provide your office with documents required to appeal the decision.**
 - a. Carefully read the documents to identify any requirements needed for the appeal. Identify if the plan set a deadline for your appeal submission.
2. **Gather supporting documentation required by the payer.**
3. **Compose the letter:** Include all information and fulfill any requirements of the patient's denial letter and laws applicable to your practice (see example letter below).
 - a. Your clinical rationale can be bolstered by attaching the full prescribing information that includes the efficacy and safety information from clinical trials.
 - The OXERVATE USPI can be found [here](#) on OXERVATE.com.
4. **Send the letter:** The letter and the supporting documentation should be sent to the plan within the **time frame designated in the denial letter.**
 - a. Review time can vary depending on the payer, however, the plan will indicate the review time in the denial letter. The patient can contact the plan to verify status of the appeal.

Important Safety Information

WARNINGS AND PRECAUTIONS

Use with Contact Lens

Contact lenses should be removed before applying OXERVATE because the presence of a contact lens (either therapeutic or corrective) could theoretically limit the distribution of cenegermin-bkjb onto the area of the corneal lesion. Lenses may be reinserted 15 minutes after administration.

Eye Discomfort

OXERVATE may cause mild to moderate eye discomfort such as eye pain during treatment. The patient should be advised to contact their doctor if a more serious eye reaction occurs.

ADVERSE REACTIONS

In clinical trials, the most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Eye pain may arise as corneal healing occurs. Other adverse reactions occurring in 1% to 10% of OXERVATE patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, photophobia, tearing, and headache.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Lactation

The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in pediatric patients 2 years of age and older is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in children.

INDICATION

OXERVATE® (cenegermin-bkjb) ophthalmic solution 0.002% (20 mcg/mL) is indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

To report ADVERSE REACTIONS, contact Dompé U.S. Inc. at 1-833-366-7387 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see [full Prescribing Information](#) for OXERVATE.

See next page for sample letter of appeal.

Physician's Letterhead

[Date]

Attn: [Contact Title/Medical Director]

[Payer Name]

[Payer Street Address]

[Payer City, State, ZIP]

Re: [Patient Full Name] appeal for coverage of
OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL)

Reference Number: [Patient's Reference Number]

Date of Birth: [Patient Date of Birth]

Member ID: [Patient ID Number]

Group Number: [Patient Group Number]

Case ID Number: [Case ID Number]

Dates of Service: [Dates]

[Name of Physician]

[Physician's Phone #]

[Physician's Address]

Dear [Payer Contact Name/Medical Director],

Please accept this letter as an appeal for [Patient's Name] in response to [Payer Name]'s decision to deny my patient coverage for OXERVATE. It is my understanding based on your letter dated [Date], that OXERVATE has been denied because [Quote the specific reason for denial stated in the denial letter].

Summary of Patient History

My patient was diagnosed with neurotrophic keratitis [Diagnosis/ICD10 code(s)].

- [Treatment history]
- [Response to past therapies]
- [Recent symptoms and condition]

[Summarize your professional opinion of the patient's likely prognosis with and without treatment with OXERVATE.]

As [Patient's Name]'s physician, I find treatment with OXERVATE medically necessary.

OXERVATE is the only FDA-approved treatment indicated for the treatment of neurotrophic keratitis (Stages 1-3).^{1,2}

I am asking [Payer Name] to reconsider the coverage decision for [Patient's Name] and approve OXERVATE treatment as quickly as possible. If you require further information or would like to speak with me directly, please contact me at [Physician's Phone #]. I appreciate your prompt action to this matter.

Sincerely,

[Treating Physician's Signature]

[Patient/Legal Representative Signature]

[Treating Physician's Name, MD/DO]

[Patient/Legal Representative Name]

Enclosures:

- Appeal form (if provided by the plan)
- Chart notes
- Test results
- Supporting medical studies
- OXERVATE® (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) Prescribing Information
- Patient narrative

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. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-neurotrophic-keratitis-rare-eye-disease>

See first page for Important Safety Information and [full Prescribing Information](#) for OXERVATE.