Cenegermin-bkbj (OXERVATE) Ophthalmic Solution

Criteria for Use

June 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive cenegermin.

- ☐ Active ocular infection
- ☐ Active ocular inflammation not related to neurotrophic keratitis
- ☐ Non-approved conditions (e.g., dry eye, glaucoma, retinitis pigmentosa)

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Provider is an ophthalmologist (VA or VA authorized community care)
- ☐ Diagnosis of stage 2 or stage 3 neurotrophic keratitis
- ☐ Refractory to treatment to regularly scheduled preservative-free artificial tears, gels, or ointments[1]
- ☐ Refractory to treatment with topical cyclosporin (if use is appropriate)
- ☐ Refractory to treatment with at least ONE of the following: corneal or scleral therapeutic contact lenses, punctal-occlusion, non-surgical (e.g., patching, botulinum induced ptosis) or surgical (tarsorrhaphy) eyelid closure, or other intervention (please list)
- ☐ Willingness to comply with cenegermin administration schedule (6 times a day at 2-hour intervals for eight weeks)[2]
- ☐ One-time renewal may be considered on a case-by-case basis for recurrence in a patient who had demonstrated compliance with the administration regimen.[3]

[1]Discontinue benzalkonium chloride (BAK)-preserved topical ophthalmic medications where feasible

[2]Discuss with patient the use of alarms or other reminders to support adherence to therapy

[3]At present there are not data on outcomes for retreatment of recurrences defined as Stage 2 or 3 NK after complete healing has occurred and the treatment has been stopped.

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