



Neurotrophic Keratitis Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Oxervate	cenegermin-bkbj ophth soln	0.002 %	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Oxervate	Cenegermin-bkbj Ophth Soln 0.002% (20 MCG/ML)	0.002 %	56	Vials	112	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Oxervate	cenegermin-bkbj ophth soln	0.002 %	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Oxervate	Cenegermin-bkbj Ophth Soln 0.002% (20 MCG/ML)	0.002 %	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of neurotrophic keratitis (NK) AND 2. The patient has stage 2 (persistent epithelial defect [PED]) or stage 3 (corneal ulcer) NK AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has NOT been previously treated with the requested agent in the affected eye(s) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient’s PED and/or corneal ulcer have been present for at least 2 weeks AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR B. The patient’s NK has been refractory to at least ONE conventional non-surgical treatment (i.e., preservative-free lubricant eye drops or ointment, discontinuation of preserved topical agents that can decrease corneal sensitivity, therapeutic soft contact lenses, topical autologous serum application, botulinum A toxin treatment) OR

Module	Clinical Criteria for Approval
	<p>C. The patient has an intolerance or hypersensitivity to at least ONE conventional non-surgical treatment for NK OR</p> <p>D. The patient has an FDA labeled contraindication to ALL conventional non-surgical treatments for NK AND</p> <p>3. The patient has decreased corneal sensitivity within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant OR</p> <p>B. The patient has been previously treated with the requested agent in the affected eye(s) AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient had complete corneal healing in the previously treated eye(s) (medical records required) AND 2. The patient has a recurrence of neurotrophic keratitis (NK) that requires another treatment course (medical records required) AND <p>4. ONE of the following:</p> <ol style="list-style-type: none"> A. The patient does NOT have ocular surface disease associated with or in conjunction with NK OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has ocular surface disease associated with or in conjunction with NK AND 2. The ocular surface disease has been properly treated AND <p>5. The patient will NOT be using the requested agent in combination with a topical ophthalmic NSAID AND</p> <p>6. The patient does NOT have any of the following:</p> <ol style="list-style-type: none"> A. Active ocular infection or active ocular inflammation not related to NK in the affected eye OR B. Severe blepharitis and/or severe Meibomian gland disease in the affected eye OR C. History of any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK OR D. Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting AND <p>7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., optometrist, ophthalmologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>8. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: 16 weeks</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND

Module	Clinical Criteria for Approval
	<p>D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] OR</p> <p>2. ALL of the following:</p> <p>A. The member resides in Ohio AND</p> <p>B. The plan is Fully Insured or HIM Shop (SG) AND</p> <p>C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>D. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND BOTH of the following: <ol style="list-style-type: none"> A. The patient has bilateral neurotrophic keratitis (NK) AND B. The requested quantity (dose) does NOT exceed TWICE the program quantity limit <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: 16 weeks</p>

