



Xdemvy Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
02-15-2026

Date of Origin
11-09-2023

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Xdemvy	lotilaner ophth soln	0.25 %	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
Xdemvy	lotilaner ophth soln	0.25 %	1	Bottle	42	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xdemvy	lotilaner ophth soln	0.25 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xdemvy	lotilaner ophth soln	0.25 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of Demodex blepharitis AND ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following signs of Demodex infestation: <ol style="list-style-type: none"> A. Collarettes (cylindrical dandruff at the eyelash base) OR B. Lid margin erythema or edema OR C. Conjunctival injection OR D. Eyelash misdirection/irregularity AND 2. ONE of the following symptoms of Demodex infestation: <ol style="list-style-type: none"> A. Blurred/fluctuating vision OR B. Discharge or crusting on lashes OR C. Dryness OR D. Foreign body sensation OR E. Itching OR F. Pain/burning OR G. Watering/tearing AND 3. The patient has ONE of the following (medical records required): <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent OR C. The patient has tried tea tree oil eyelid scrubs for at least 6 weeks and had an inadequate response OR D. Tea tree oil eyelid scrubs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR E. The patient has an intolerance or hypersensitivity to tea tree oil eyelid scrubs OR F. The patient has an FDA labeled contraindication to tea tree oil eyelid scrubs OR G. Tea tree oil eyelid scrubs are expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm OR

Module	Clinical Criteria for Approval
	<p>H. Tea tree oil eyelid scrubs are not in the best interest of the patient based on medical necessity OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as tea tree oil eyelid scrubs and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR</p> <p>B. The patient has an FDA labeled indication for the requested agent and route of administration OR</p> <p>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., ophthalmologist, optometrist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months All other plans: 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE the following are met:</p> <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul 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 <p>2. ALL of the following:</p> <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ul 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]

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	<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 All other plans: 12 months</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 ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <p>Length of Approval:</p> <p>BCBSIL: 12 months All other plans: 6 months</p>