

Actinic Keratosis Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

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
		5 %	M ; N ; O	Y		
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	M ; N ; O ; Y	Y		
Carac ; Fluorouracil	Fluorouracil Cream 0.5%	0.5 %	M ; N ; O ; Y	M ; N		
Tolak	Fluorouracil Cream 4%	4 %	M ; N ; O ; Y	N		
Efudex	Fluorouracil Cream 5%	5 %	M ; N ; O ; Y	O ; Y		
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	M ; N ; O ; Y	N		
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	M ; N ; O ; Y	O ; Y		
Klisyri	tirbanibulin ointment	1 %	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
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	300	Grams	90	DAYS			
	Imiquimod Cream 5%	5 %	48	Packets	112	DAYS			
Carac ; Fluorouracil	Fluorouracil Cream 0.5%	0.5 %	30	Grams	28	DAYS			
Efudex	Fluorouracil Cream 5%	5 %	240	Grams	84	DAYS			
Klisyri	Tirbanibulin Ointment	1 %	5	Packets	90	DAYS			
Tolak	Fluorouracil Cream 4%	4 %	40	Grams	28	DAYS			
Zyclara	imiquimod cream	3.75 %	56	Packets	42	DAYS			516724 17406;9 920702 7028
Zyclara pump	imiquimod cream	3.75 %	2	Bottles	42	DAYS			000933 13331;5 167241 7409;63 629881

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
									801 ; 686820 27275 ; 992070 27175
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	2	Bottles	42	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
		5 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Carac ; Fluorouracil	Fluorouracil Cream 0.5%	0.5 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Efudex	Fluorouracil Cream 5%	5 %	IL HMO Performance Annual ; Basic ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Klisyri	tirbanibulin ointment	1 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Tolak	Fluorouracil Cream 4%	4 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	IL HMO Performance Annual ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	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
	Imiquimod Cream 5%	5 %	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
Carac ; Fluorouracil	Fluorouracil Cream 0.5%	0.5 %	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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Efudex	Fluorouracil Cream 5%	5 %	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
Klisyri	Tirbanibulin Ointment	1 %	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
Tolak	Fluorouracil Cream 4%	4 %	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Zyclara	imiquimod cream	3.75 %	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
Zyclara pump	imiquimod cream	3.75 %	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
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; 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
PA	<p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient’s age for the requested indication AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: AND 2. The requested agent is diclofenac 3% gel, Carac (fluorouracil) 0.5% cream, Efudex (fluorouracil) 5% cream, Tolak (fluorouracil) 4% cream, Aldara (imiquimod) 5% cream, Zyclara (imiquimod) 3.75% cream, Zyclara (imiquimod) 2.5% cream, or Klisyri (tirbanibulin) 1% ointment OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: AND 2. The requested agent is diclofenac 3% gel or Efudex (fluorouracil) 5% cream OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of superficial basal cell carcinoma AND 2. The requested agent is Aldara (imiquimod) 5% cream or Efudex (fluorouracil) 5% cream OR D. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of external genital and/or perianal warts (EGW)/ condyloma acuminata AND 2. The requested agent is Aldara (imiquimod) 5% cream or Zyclara (imiquimod) 3.75% cream AND 3. ONE of the following: <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. BOTH of the following <ol style="list-style-type: none"> 1. ONE of the following:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that 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 are 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 <p>C. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR 2. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution [chart notes are required] OR 3. Generic imiquimod 5% cream or fluorouracil solution was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 4. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution [chart notes are required] OR 5. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution [chart notes are required] OR 6. Generic imiquimod 5% cream or fluorouracil solution is 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 [chart notes are required] OR 7. Generic imiquimod 5% cream or fluorouracil solution is not in the best interest of the patient based on medical necessity [chart notes are required] OR 8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as generic imiquimod 5% cream or fluorouracil solution and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR <p>D. For a diagnosis of external genital warts, ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR 2. The patient has tried and had an inadequate response to generic imiquimod 5% cream [chart notes are required] OR 3. Generic imiquimod 5% cream was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 4. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream [chart notes are required] OR 5. The patient has an FDA labeled contraindication to generic imiquimod 5% cream [chart notes are required] OR 6. Generic imiquimod 5% cream is 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

Module	Clinical Criteria for Approval
	<p>performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR</p> <ol style="list-style-type: none"> 7. Generic imiquimod 5% cream is not in the best interest of the patient based on medical necessity [chart notes are required] OR 8. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as generic imiquimod 5% cream and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans: 4 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. ONE of the following: <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
QL	<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 OR2. There is support for therapy with the requested quantity (dose) for the requested indication <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: 4 months</p>