



Zoryve Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date

02-01-2026

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
Zoryve	roflumilast cream	0.05 % ; 0.15 % ; 0.3 %	M ; N ; O ; Y	N		
Zoryve	roflumilast foam	0.3 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zoryve	roflumilast cream	0.05 % ; 0.15 % ; 0.3 %	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 HMO Performance Quarterly ; 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
Zoryve	roflumilast foam	0.3 %	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 HMO Performance Quarterly ; 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

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy OR 2. ONE topical calcineurin inhibitor used in the treatment of AD was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR 3. The patient has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD OR 4. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD OR 5. ONE topical calcineurin inhibitor used in the treatment of AD 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 OR 6. ONE topical calcineurin inhibitor used in the treatment of AD is not in the best interest of the patient based on medical necessity OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE topical calcineurin inhibitor used in the treatment of AD and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event AND <ol style="list-style-type: none"> 2. BOTH of the following: <ol style="list-style-type: none"> A. The patient is currently treated with topical emollients and practicing good skin care AND B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent OR <p>B. The patient has a diagnosis of plaque psoriasis AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE topical corticosteroid used in the treatment of plaque psoriasis after at least a 2-week duration of therapy OR ONE topical calcineurin inhibitor used in the treatment of plaque psoriasis OR B. An intolerance or hypersensitivity to ONE topical corticosteroid OR ONE topical calcineurin inhibitor used in the treatment of plaque psoriasis OR C. An FDA labeled contraindication to ALL topical corticosteroids AND ALL topical calcineurin inhibitors used in the treatment of plaque psoriasis AND <p>C. The patient has a diagnosis of seborrheic dermatitis AND ONE of the following:</p> <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. 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 patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to

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	<p style="text-align: center;">stage four advanced metastatic cancer [chart notes required] AND</p> <p>B. 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> <p>2. BOTH of the following:</p> <p>A. The patient has ONE of the following:</p> <ol style="list-style-type: none"> 1. Tried and had an inadequate response to ONE topical antifungal used in the treatment of seborrheic dermatitis OR 2. An intolerance or hypersensitivity to ONE topical antifungal used in the treatment of seborrheic dermatitis OR 3. An FDA labeled contraindication to ALL topical antifungals used in the treatment of seborrheic dermatitis AND <p>B. The patient has ONE of the following:</p> <ol style="list-style-type: none"> 1. Tried and had an inadequate response to ONE topical corticosteroid used in the treatment of seborrheic dermatitis OR 2. Tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) used in the treatment of seborrheic dermatitis OR 3. An intolerance or hypersensitivity to ONE topical corticosteroid or topical calcineurin inhibitor used in the treatment of seborrheic dermatitis OR 4. Seborrheic dermatitis of the scalp AND an FDA labeled contraindication to ALL topical corticosteroids used in the treatment of seborrheic dermatitis OR 5. An FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors used in the treatment of seborrheic dermatitis OR <p>D. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>3. If the patient has an FDA labeled indication, then ONE of the following:</p> <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 <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <ul style="list-style-type: none"> • BCBSOK: 36 months • Diagnosis of atopic dermatitis or seborrheic dermatitis: BCBSIL and BCBSMT 12 months; ALL other plans 3 months • Diagnosis of plaque psoriasis and ALL other indications: 12 months <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"> a. The patient does NOT have any FDA labeled contraindications to the requested agent AND

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	<p>b. ONE of the following:</p> <ul style="list-style-type: none"> i. The patient has another FDA labeled indication for the requested agent and route of administration OR ii. The patient has another indication that is supported in compendia for the requested agent and route of administration OR iii. 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>Renewal Evaluation</p> <ul style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan’s Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND 3. If the patient has a diagnosis of mild to moderate atopic dermatitis, then the patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent AND 4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., dermatologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p>