

Zoryve (roflumilast) Prior Authorization

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Zoryve™ (roflumilast) Cream	Treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older		1

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Psoriasis (PS)	<p>Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful. Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.(2)</p> <p>The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:(2)</p> <ul style="list-style-type: none"> • Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face): <ul style="list-style-type: none"> ○ Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac) ○ Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus) • Severe (5% or more of BSA or involving the genitals, hands, feet, and face): <ul style="list-style-type: none"> ○ Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids ○ 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA • Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin <p>The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes</p>
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	<p>intractable pruritus.(4) The AAD psoriasis treatment guidelines recommend the following:(3,6)</p> <ul style="list-style-type: none"> • Limited disease (less than 5% of BSA): <ul style="list-style-type: none"> ○ Topical corticosteroids are first line as either monotherapy or in conjunction with non-steroidal topical agents ○ Vitamin D analogs, calcipotriene, calcipotriol, and calcitriol, are other first line agents and are often used in combination with topical corticosteroids ○ Tazarotene is a corticosteroid sparing agent and can be used in combination with topical corticosteroids to produce a synergistic effect and longer durations of treatment benefit and remission ○ Phototherapy is another first line option for limited disease, and allows for selective targeting of localized lesions and resistant areas such as the scalp and skin folds, leaving surrounding, non-lesional skin unaffected ○ Calcineurin inhibitors (tacrolimus and pimecrolimus) may also be considered first line for intertriginous, inverse, face, and genital psoriasis ○ Systemic agents are considered second line and only for short term use • Moderate to severe disease without PsA (more than 5% of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life): <ul style="list-style-type: none"> ○ UV-therapy is considered first line as monotherapy or in combination with acitretin or MTX ○ If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics ○ Second line systemic agents include leflunomide, sulfasalazine, and tacrolimus • Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA <p>The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:(5)</p> <ul style="list-style-type: none"> • The preferred assessment instrument for determining disease severity is BSA • Target response after treatment initiation should be BSA less than or equal to 1% after 3 months • Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation
Efficacy (1)	<p>Two multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 [NCT04211363] and DERMIS-2 [NCT04211389]) enrolled a total of 881 subjects with mild to severe plaque psoriasis and an affected BSA of 2% to 20%. At baseline, 16% of subjects had an Investigator’s Global Assessment (IGA) score of 2 (mild), 76% had an IGA score of 3 (moderate), and 8% had an IGA score of 4 (severe). One hundred seventy-nine (20%) subjects had an intertriginous IGA (I-IGA) score of 2 or higher (mild) at baseline, and 678 (77%) subjects had a baseline Worst Itch-Numeric Rating Score (WI-NRS) score of 4 or higher on a scale of 0 to 10.</p> <p>Subjects were randomized 2:1 to receive Zoryve or vehicle applied once daily for 8 weeks. The primary endpoint was the proportion of subjects who achieved IGA treatment success at week 8. Success was defined as a score of “Clear” (0) or “Almost Clear” (1), plus a 2-grade improvement from baseline. Secondary endpoints included</p>

	<p>the proportion of subjects that achieved I-IGA success at week 8 and WI-NRS success sequentially at weeks 8, 4, and 2. WI-NRS success was defined as a reduction of at least 4 points from baseline in subjects with a baseline WI-NRS score of at least 4.</p> <p>Patients treated with Zoryve achieved greater IGA success at week 8 compared to patients treated with vehicle (41.5% vs 5.8% [difference of 39.7% for DERMIS-1], 36.7% vs 7.1% [difference of 29.5% for DERMIS-2]. Among subjects with an I-IGA score of at least 2 (mild) at baseline (approximately 22% of subjects in DERMIS-1 and 19% in DERMIS-2), there was a higher percentage of subjects who achieved I-IGA success at week 8 in the group who received Zoryve compared to the group who received vehicle (DERMIS-1: 71.5% vs. 13.8%; DERMIS-2: 67.5% vs. 17.4%). Secondary endpoints were not statistically significant.</p>
Safety (1)	Zoryve is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

REFERENCES

Number	Reference
1	Zoryve prescribing information. Arcutis Biotherapeutics, Inc. July 2022.
2	Weigle, Nancy, M.D., et al. Psoriasis. American Academy of Family Physicians. May 2013. 87 (9): 626-633.
3	Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2011;65(1):137–174.
4	Menter, Alan et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. doi: https://doi.org/10.1016/j.jaad.2018.11.057 .
5	Armstrong AW, Siegel MP, Bagel J, et al. From the medical board of the National Psoriasis Foundation: treatment targets for plaque psoriasis. Journal of the American Academy of Dermatology. 2017;76(2):290-298. doi: 10.1016/j.jaad.2016.10.017.
6	Menter A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2008; 58:826–850. doi: 10.1016/j.jaad.2008.02.039.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Preferred Status	Effective Date
	902500450037	Zoryve	Roflumilast Cream	0.3 %	M ; N ; O ; Y			02-15-2023

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Client Formulary
Zoryve	Roflumilast Cream	0.3 %	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <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 plaque psoriasis AND 2. The patient's affected body surface area (BSA) is less than or equal to 20% AND 3. 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to a topical corticosteroid OR B. The patient has an intolerance or hypersensitivity to therapy with topical corticosteroids OR C. The patient has an FDA labeled contraindication to ALL topical corticosteroids AND 5. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to another topical psoriasis agent with a different mechanism of action (e.g., vitamin D analogs, calcineurin inhibitors, tazarotene) OR B. The patient has an intolerance or hypersensitivity to another topical psoriasis agent with a different mechanism of action OR C. The patient has an FDA labeled contraindication to ALL other topical psoriasis agents with a different mechanism of action AND 6. 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 7. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval: 12 months</p> <p>Renewal Evaluation</p>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND 2. The patient has had clinical benefit with the requested agent AND 3. 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 4. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval: 12 months</p>

PRIOR AUTHORIZATION CLINICAL CRITERIA OPERATIONAL LEVEL OF EVIDENCE REQUIREMENTS

Module	Ops Set Up	Validation Options	Other Explanation
	Validation: Apply Baseline and go to Validation Options	Age Verification;Contraind., intolerance, or hypersensitivity to prereq.	

DOCUMENT HISTORY

Approval Date MM/YYYY	Approved By	Notes
11-2022	P&T UM Committee	Original Prime Standard criteria
12-2022		Administrative Action (correction of BSA requirement to include affected)
12-2022	BCBS KS	Document History -BCBS KS Original Client Specific Review Prime Standard criteria, approved by BCBS KS 12/2022 Original Implementation 02/15/2023
12-2022		Administrative Action (note policy applies to ResultsRx)

NOTES FOR OPERATIONS

CO Notes	Date Created	Last Date ANY Field Changed
This program applies to Commercial, HIM and ResultsRx.	12/23/2022 10:17:32 AM	12/23/2022 10:30:45 AM

POLICY REVIEW CYCLE

Effective Date 3/1/2023	Date of Origin	Status Draft
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