

Zoryve (roflumilast)
Effective 06/14/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Zoryve (roflumilast) is a phosphodiesterase 4 inhibitor. It is available in a number of strengths and formulations, each with its own indication:

- **0.05% cream:** topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age
- **0.15% cream:** topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older
- **0.3% cream:** topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older
- **0.3% foam:** topical treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older, as well as plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following diagnosis-specific criteria are met:

Zoryve 0.05%, 0.15% Cream:

1. ONE of the following:
 - a. Member is 6 years of age or older and request is for Zoryve 0.15% cream
 - b. Member is 2 to 5 years of age and request is for Zoryve 0.05% cream
2. Diagnosis of mild to moderate atopic dermatitis
3. Member meets ONE of the following:
 - a. Member has had an inadequate response or intolerance to ONE of the following:
 - i. Medium or higher potency topical corticosteroids (see Appendix)
 - ii. Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
 - b. Member has a contraindication to both topical corticosteroids and topical calcineurin inhibitors

Zoryve 0.3% Cream:

1. Member is 6 years of age or older
2. Diagnosis of plaque psoriasis
3. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies:
 - a. Corticosteroids (e.g., betamethasone, clobetasol)
 - b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
 - c. Tazarotene
 - d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
 - e. Anthralin
 - f. Coal tar

Zoryve 0.3% Foam:**Seborrheic Dermatitis**

1. Member is 9 years of age or older
2. Member has a diagnosis of seborrheic dermatitis
3. Member meets ONE of the following:
 - a. Member has a diagnosis of **non-scalp seborrheic dermatitis** and has had an inadequate treatment response or intolerance to at least one agent in all three of the following classes or prescriber provides a clinical rationale why none of the following classes is clinically appropriate:
 - i. Corticosteroids (e.g., betamethasone, clobetasol)
 - ii. Antifungals (e.g., ciclopirox, ketoconazole)
 - iii. Calcineurin inhibitors (e.g., tacrolimus)
 - b. Member has a diagnosis of **seborrheic dermatitis of the scalp** and has had an inadequate treatment response or intolerance to at least one agent in both of the following classes or the prescriber provides a clinical rationale why none of the following classes is clinically appropriate:
 - i. Corticosteroids (e.g., betamethasone, clobetasol)
 - ii. Antifungals (e.g., ciclopirox, ketoconazole)

Plaque Psoriasis

1. Member is 12 years of age or older
2. Diagnosis of plaque psoriasis
3. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies:
 - a. Corticosteroids (e.g., betamethasone, clobetasol)
 - b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
 - c. Tazarotene
 - d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
 - e. Anthralin
 - f. Coal tar

Continuation of Therapy

Requests for reauthorization will be approved when all of the following diagnosis-specific criteria are met:

Atopic Dermatitis:

1. Submission of medical records (e.g., chart notes) documenting clinical improvement in member's condition as evidenced by low disease activity (e.g., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).



Plaque Psoriasis, Seborrheic Dermatitis:

1. Submission of medical records (e.g., chart notes) documenting clinical improvement in member’s condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Drug Name, Strength, and Dosage Form	Quantity Limit
Zoryve 0.05% cream	60 grams per 30 days
Zoryve 0.15% cream	60 grams per 30 days
Zoryve 0.3% cream	60 grams per 30 days
Zoryve 0.3% foam	60 grams per 30 days

Appendix

Appendix: Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
Super-high potency	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
High potency	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
Halobetasol propionate	Lotion	0.01%	
High potency	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
Fluocinonide	Cream, aqueous emollient	0.05%	



Potency	Drug	Dosage form	Strength
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
Medium potency	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
Aerosol Spray		0.2 mg per 2-second spray	

References

1. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71:116-32.
2. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol.* 2021; 84(2):432-470.
3. Menter A, Cordoro K, Davis D, et al. Guidelines of Care for the Management and Treatment of Psoriasis in Pediatric Patients. *J Am Acad Dermatol.* 2020;82(1):161-201.
4. Sasseville D. Seborrheic dermatitis in adolescents and adults. UpToDate. Available at: www.uptodate.com. Accessed 21 June 2024.
5. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. August 16, 2021. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed August 9, 2022.
6. Zoryve (roflumilast) cream [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.
7. Zoryve (roflumilast) foam [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.

Review History

01/11/2023: Created and Reviewed at January P&T. Effective 02/01/23

07/10/2024: Reviewed and updated for July P&T; added Zoryve 0.3% foam to criteria; updated Zoryve cream criteria to reduce minimum age to 6 years of age; clarified that members are considered new to the Plan if they joined within the previous 90 days; Effective 10/01/2024.

09/11/2024 – Reviewed and updated for September P&T. Added criteria for Zoryve 0.15% cream to the policy. Added appendix with relative potency of select topical corticosteroids. Effective 11/01/2024.

02/11/2026 – Reviewed and updated for February P&T. Added Zoryve 0.05% cream to the policy and updated Zoryve criteria for atopic dermatitis to allow for approval of the 0.05% cream for members 2 to 5 years of age.



Updated criteria for 0.3% cream for plaque psoriasis to require minimum 4-week trial of one of the following: corticosteroids (e.g., betamethasone, clobetasol), vitamin D analogs (e.g., calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), anthralin, or coal tar; removed the ability to bypass previous trial if psoriasis is on sensitive area. Added supplemental indication of plaque psoriasis for Zoryve foam. Updated reauthorization criteria to require documentation of improvement. Effective 06/14/2026.

04/15/2026 – Reviewed and updated for April P&T. Updated atopic dermatitis criteria to require trial and failure with either medium to high potency topical corticosteroid or topical calcineurin inhibitor. Updated approval length to 12 months. Effective 06/14/2026.

