

Zoryve (roflumilast)
Effective 11/01/2024

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

- **0.15% 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

Coverage Guidelines

Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, 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 criteria are met, and documentation is provided:

Zoryve 0.15% Cream:

1. The member is 6 years of age or older
2. The member has a diagnosis of mild to moderate atopic dermatitis
3. The 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
 - ii. Calcineurin inhibitors: Pimecrolimus cream OR tacrolimus ointment
 - iii. Eucrisa (crisaborole) ointment
 - b. Member has a contraindication to topical corticosteroids, calcineurin inhibitors, and Eucrisa

Zoryve 0.3% Cream:

1. The member is 6 years of age or older
2. The member has a diagnosis of plaque psoriasis

3. The member meets ONE of the following:
 - a. The member has had inadequate treatment response, intolerance or has contraindication to a topical steroid
 - b. The medication will be used on sensitive skin area (e.g., face, genitals, or skin folds)

Zoryve 0.3% Foam:

1. The member is 9 years of age or older
2. The member has a diagnosis of seborrheic dermatitis
3. The member meets ONE of the following:
 - a. The 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. The 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)

Continuation of Therapy

Reauthorization requires the member to meet all initial criteria and physician documentation of improvement of member's condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.
2. The following quantity limits apply:

Drug Name	Quantity Limit
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%



Potency	Drug	Dosage form	Strength
	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%
High potency	Halobetasol propionate	Lotion	0.01%
	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%
	Fluticasone propionate	Ointment	0.005%
Medium potency	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
	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. Elmetts 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, Cordero 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 [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.
7. Zoryve (roflumilast) foam [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.

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.

