

# Zoryve (roflumilast) Effective 10/01/2024

Plan	☐ MassHealth UPPL  ⊠Commercial/Exchange	D	⊠ Prior Authorization	
Benefit	<ul><li>☑ Pharmacy Benefit</li><li>☐ Medical Benefit</li></ul>	Program Type	☐ Quantity Limit ☐ Step Therapy	
Specialty Limitations	N/A			
	Medical and Specialty Medications			
Contact Information	All Plans	Phone: 877-519-1908	Fax: 855-540-3693	
	Non-Specialty Medications			
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

#### Overview

Zoryve (roflumilast) 0.3% cream is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

Zoryve (roflumilast) 0.3% foam is indicated for the 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 and is stable on Zoryve 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 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 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 0.3% cream	60 grams per 30 days	
Zoryve 0.3% foam	60 grams per 30 days	

#### 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 [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; January 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.

