Zoryve (roflumilast)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zoryve (roflumilast) 0.3% cream, foam Zoryve (roflumilast) 0.15% cream	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Zoryve (roflumilst) 0.3% cream may be approved if the following criteria are met:

I. Individual has a diagnosis of plaque psoriasis; **AND**
II. Individual has had a trial of and inadequate response or intolerance to TWO of the following topical therapies from different classes for psoriasis* (AAD 2020). [A combination agent with two different classes (for example, calcipotriene/betamethasone) is accepted as a trial of two]. Medication samples/coupons/discount cards are excluded from consideration as a trial:
    A. Medium to high potency topical corticosteroids; **OR**
    B. Tazarotene; **OR**
    C. Vitamin D analogs (calcitriol, calcipotriene, or calcipotriene/betamethasone combination agents); **OR**
    D. Topical calcineurin inhibitors (tacrolimus or pimecrolimus); **OR**
    E. Salicylic acid; **OR**
    F. Anthralin; **OR**
    G. Coal tar preparations.

    *Some therapies may be subject to Prior Authorization.

Requests for Zoryve (roflumilst) 0.3% foam may be approved if the following criteria are met:

I. Individual has a diagnosis of seborrheic dermatitis; **AND**
II. Individual has moderate to severe (IGA score of 3 or higher) disease (NCT04973228, NCT04091646); **AND**
III. Individual has had a trial of and inadequate response or intolerance to one agent from each of the following classes for seborrheic dermatitis*:
    A. Topical corticosteroid; **AND**
    B. Topical antifungal agent (such as ketoconazole or clotrimazole).

    *Some therapies may be subject to Prior Authorization.

Requests for Zoryve (roflumilast) 0.15% cream may be approved if the following criteria are met:

I. Individual has a diagnosis of mild to moderate atopic dermatitis; **AND**
II. Individual has had a trial of and inadequate response or intolerance to one agent from each of the following classes for atopic dermatitis* or individual has a clinical reason why they cannot be used:
    A. Topical calcineurin inhibitor; **AND**
    B. Topical corticosteroid

*Some therapies may be subject to Prior Authorization.

Requests for Zoryve (roflumilst) may not be approved for the following:

I. Individual has moderate or severe liver impairment (Child-Pugh class B or C).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. Eichenfield L. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. Journal of the American Academy of Dermatology. 2014-01;71:116.
5. Elmets CA, Korman NJ, Prater EF, Wong EB, Rupani RN, Kivelevitch D, 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, Journal of the American Academy of Dermatology (2020), doi: https://doi.org/10.1016/j.jaad.2020.07.087.
6. Sidbury, Robert et al. “Guidelines of care for the management of atopic dermatitis in adults with topical therapies.” Journal of the American Academy of Dermatology vol. 89,1 (2023): e1-e20. doi:10.1016/j.jaad.2022.12.029