

STEP THERAPY POLICY

- POLICY:** Topical Agents for Atopic Dermatitis Step Therapy Policy
- Elidel[®] (pimecrolimus 1% cream – Bausch Health/Valeant, generic)
 - Eucrisa[®] (crisaborole 2% ointment – Pfizer)
 - Protopic[®] (tacrolimus 0.03% and 0.1% ointment – LEO, generic)
 - Zoryve[®] (roflumilast 0.15% cream – Arcutis)

REVIEW DATE: 10/23/2024

OVERVIEW

Tacrolimus ointment and pimecrolimus cream are topical calcineurin inhibitors that are indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of **atopic dermatitis** in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.^{1,2} Tacrolimus ointment is indicated for moderate to severe atopic dermatitis while pimecrolimus cream is indicated for mild to moderate atopic dermatitis. Eucrisa and Zoryve 0.15% cream, topical phosphodiesterase 4 inhibitors, are indicated for the topical treatment of mild to moderate **atopic dermatitis**.^{3,7}

Tacrolimus 0.03% ointment and pimecrolimus cream are indicated for use in adults and children ≥ 2 years of age.^{1,2} Although there are data documenting the tacrolimus 0.1% strength's safety and efficacy in children, this product is not approved for use in pediatric patients. Neither tacrolimus 0.03% ointment nor pimecrolimus cream are indicated for use in children < 2 years of age; however, both agents have been studied in this patient population. Eucrisa is indicated for use in patients ≥ 3 months of age.³ Zoryve 0.15% cream is indicated for use in patients ≥ 6 years of age.⁷

Topical corticosteroids are generally indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.⁴

Guidelines

The American Academy of Dermatology (AAD) Guidelines of Care for the Management of Atopic Dermatitis in Adults with Topical Therapies (2023) recommend the use of topical corticosteroids and note that these products are commonly used as first-line topical treatment as they suppress the release of proinflammatory cytokines and target a variety of immune cells.⁵ Topical calcineurin inhibitors (i.e., tacrolimus ointment and pimecrolimus cream) are noted to be a safe topical anti-inflammatory option, particularly if topical corticosteroid adverse events are of concern. Tacrolimus ointment is recommended for use in all adults with atopic dermatitis, while pimecrolimus cream is a recommended treatment option for patients with mild-to-moderate disease. Similarly, Eucrisa is a recommended treatment option for adults with mild-to-moderate atopic dermatitis. Zoryve 0.15% cream is not addressed.

Recommendations for the management of pediatric patients have not been updated. However, AAD guidelines from 2014 make similar recommendations regarding the use of topical corticosteroids and topical calcineurin inhibitors in pediatric patients.⁶ Eucrisa and Zoryve 0.15% cream are not addressed.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: prescription topical corticosteroids (brand or generic)

Step 2: generic pimecrolimus 1% cream, Elidel, Eucrisa, generic tacrolimus ointment (0.03% and 0.1% strengths), Protopic, Zoryve 0.15% cream

CRITERIA

1. If the patient has tried a Step 1 Product, approve a Step 2 Product.
2. If the patient has a dermatologic condition on or around the face, eyes/eyelids, axilla, or genitalia, approve a Step 2 Product.
3. If the patient is < 2 years of age, approve Eucrisa.
4. No other exceptions are recommended.

REFERENCES

1. Elidel® cream [prescribing information]. Bridgewater, NJ: Bausch/Valeant; September 2020.
2. Protopic® ointment [prescribing information]. Madison, NJ: LEO; June 2022.
3. Eucrisa® ointment [prescribing information]. New York, NY: Pfizer; January 2024.
4. Triamcinolone acetonide cream [prescribing information]. Hawthorne, NY: Taro; February 2023.
5. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol.* 2023;89(1):e1-e20.
6. Eichenfield LF, Tom WL, Berger TG, 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(1):116-132.
7. Zoryve® cream [prescribing information]. Westlake Village, CA: Arcutis; July 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/20/2023
Early Annual Revision	Zoryve 0.15% cream: Zoryve 0.15% cream was added to Step 2.	10/23/2024