

STEP THERAPY POLICY

- POLICY:** Topical Agents for Atopic Dermatitis Step Therapy Policy
- Elidel[®] (pimecrolimus 1% cream – Valeant, generics)
 - Eucrisa[®] (crisaborole 2% ointment – Pfizer)
 - Protopic[®] (tacrolimus 0.03% and 0.1% ointment – Astellas/LEO Pharma, generics)

REVIEW DATE: 11/11/2020

OVERVIEW

Tacrolimus ointment and pimecrolimus cream are topical calcineurin inhibitors (immunomodulators) 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. Tacrolimus 0.03% ointment and pimecrolimus cream are indicated in adults and children ≥ 2 years of age. 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 ointment nor pimecrolimus cream are indicated for use in children < 2 years of age; however, both agents have been studied in this patient population.³ Eucrisa, a phosphodiesterase 4 inhibitor, is indicated for the topical treatment of mild to moderate **atopic dermatitis** in patients ≥ 3 months of age of age.⁴ Topical corticosteroids are generally indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.⁶

Guidelines

According to the 2012 Joint Task Force (American Academy of Allergy, Asthma, and Immunology [AAAAI], the American College of Allergy, Asthma, and Immunology [ACAAI], and the Joint Council of Allergy, Asthma, and Immunology [JCAAI]) Atopic Dermatitis Practice Parameter and the 2014 American Academy of Dermatology (AAD) Guidelines of Care for the Management of Atopic Dermatitis make similar recommendations with regard to the topical treatment of atopic dermatitis.^{3,5} Moisturizers should be recommended as first-line therapy. For disease that is not controlled by moisturizers alone, a topical corticosteroid should be used, with the exception that potent fluorinated corticosteroids should not be used on the face, eyelids, genitalia, and intertriginous areas or in young infants. A low-potency corticosteroid preparation is generally recommended for these areas. The Joint Task Force practice parameter notes that tacrolimus ointment should be considered for atopic that is unresponsive to low-potency topical steroids.³ Tacrolimus ointment, unlike topical glucocorticoids, is not atrophogenic and has a greater therapeutic margin of safety than medium-strength corticosteroids for facial and eyelid eczema. Tacrolimus 0.1% ointment should be considered first-line therapy for facial eczema where treatment with corticosteroids is limited to low-potency corticosteroids due to safety concerns. According to guidelines, pimecrolimus cream is also efficacious and does not cause skin atrophy. The AAD guidelines confirm that both of the topical immunomodulators are effective for acute and chronic AD treatment, especially in patients with steroid-refractory atopic dermatitis, atopic dermatitis in sensitive areas (e.g., face, genitalia, skin folds), steroid-induced atrophy, and long-term uninterrupted topical steroid use.⁵ Neither the Joint Practice Parameter nor the AAD guidelines have been updated to address Eucrisa.

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

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: Valeant Pharmaceuticals North American LLC; March 2014.
2. Protopic[®] ointment [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; May 2012.
3. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013;131:295-299.
4. Eucrisa[™] ointment [prescribing information]. Palo Alto, CA and New York, NY: Anacor Pharmaceuticals and Pfizer; March 2020.
5. 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.
6. Triamcinolone acetonide cream [prescribing information]. Bronx, NY: Perrigo New York, Inc.; October 2018.