PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/15/2018
LAST REVIEW DATE: 2/17/2022
LAST CRITERIA REVISION DATE: 2/17/2022
ARCHIVE DATE:

ELIDEL® (pimecrolimus) cream
EUCRISA™ (crisaborole) ointment
PROTOPIC® (tacrolimus) ointment

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

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864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

EUCRISA (crisaborole) ointment

- **Criteria for initial therapy: Eucrisa (crisaborole) 2% ointment** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

  2. A confirmed diagnosis of mild to moderate atopic dermatitis

  3. Individual is **ONE** of the following:
     a. **3 months to 2 years of age** with involvement of non-facial non-skinfold areas who has failure, contraindication per FDA label, or intolerance to **at least 2** low to medium potency (brand or generic) corticosteroids (strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. See Definition section)

     b. **3 months to 2 years of age** with involvement of the face, eyelids, neck, genitalia, or intertriginous areas

     c. **2 years of age or older** who has failure, contraindication per FDA label or intolerance to **BOTH** of the following:
        i. **At least 2** low to medium potency or medium to high potency (brand or generic) corticosteroids (strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. See Definition section) **AND**
        ii. Failure, contraindication per FDA label, or intolerance to both topical tacrolimus and topical pimecrolimus

  Initial approval duration: 60 gm tube for 30 days only

- **Criteria for continuation of coverage (renewal request): Eucrisa (crisaborole) 2% ointment** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

  2. Individual's condition has not worsened while on therapy
     a. Worsening is defined as:

i. Red, scaly, itchy and crusted bumps
ii. Seelling, cracking, "weeping" clear fluid
iii. Coarsening and thickening of the skin

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use

Renewal duration: 60 gm tube for 30 days only

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-cancer Medications**

2. **Off-Label Use of Cancer Medications**

ELIDEL (pimecrolimus) cream
PROTOPIC (tacrolimus) ointment

- **Criteria for initial therapy: Elidel (pimecrolimus) cream or Protopic (tacrolimus) ointment** are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. **ONE** of the following:
   a. **For brand Elidel (pimecrolimus) 1% cream**: A confirmed diagnosis of mild to moderate atopic dermatitis in a non-immunocompromised individual 2 years of age or older

   b. **For Protopic (tacrolimus) 0.03% ointment**: A confirmed diagnosis of moderate to severe atopic dermatitis in a non-immunocompromised individual 2 years of age or older

   c. **For Protopic (tacrolimus) 0.1% ointment**: A confirmed diagnosis of moderate to severe atopic dermatitis in a non-immunocompromised individual 18 years of age or older

3. Individual who has failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable

4. Individual has failure, contraindication per FDA label or intolerance to:
   a. **For brand Elidel (pimecrolimus) 1% cream ONE** of the following**:**
      i. Generic pimecrolimus 1% cream **OR**

ii. Generic tacrolimus 0.03% cream **OR**
iii. Eucrisa (crisaborole) 2% ointment

b. **For brand Protopic (tacrolimus) 0.03% ointment ONE** of the following**:**
i. Generic tacrolimus 0.03% ointment **OR**
ii. Eucrisa (crisaborole) 2% ointment

c. **For brand Protopic (tacrolimus) 0.1% ointment:** generic tacrolimus 0.1% ointment

5. Individual has failure, contraindication per FDA label or intolerance to **at least 2** of the preferred medium to high potency topical corticosteroids:
   a. Amcinonide 0.1% ointment or cream
   b. Diprolene (betamethasone dipropionate, augmented) 0.05% ointment or cream
   c. Betamethasone dipropionate 0.05% cream or valerate 0.1% ointment
   d. Temovate (clobetasol propionate) 0.05% ointment or cream
   e. Cloderm (clocortolone pivalate) 0.1% cream
   f. Topicort (desoximetasone) 0.25% ointment or cream
   g. Topicort (desoximetasone) 0.5% cream
   h. ApexiCon (diflorasone diacetate) 0.05% ointment or cream
   i. ApexiCon E (diflorasone diacetate, emollient) 0.05% cream
   j. Synalar (fluocinolone) 0.025% ointment
   k. Vanos (fluocinonide) 0.1% cream
   l. Fluocinonide 0.05% ointment or cream
   m. Cordran SP (flurandrenolide) 0.05% cream
   n. Cutivate Fluticasone propionate 0.005% ointment
   o. Cutivate Fluticasone propionate 0.05% cream
   p. Halog (halcinonide) 0.1% ointment or cream
   q. Ultravate (halobetasol propionate) 0.05% ointment or cream
   r. Elocon (mometasone furoate) 0.1% cream
   s. Dermatop (prednicarbate) 0.1% ointment or cream
   t. Triamcinolone acetonide 0.5% ointment or cream
   u. Triamcinolone acetonide 0.1% ointment or cream

Initial approval duration: 30 gm tube for 30 days only

- **Criteria for continuation of coverage (renewal request): Elidel (pimecrolimus) cream or Protopic (tacrolimus) ointment** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual's condition has not worsened while on therapy

a. Worsening is defined as:
   i. Red, scaly, itchy and crusted bumps
   ii. Seelling, cracking, "weeping" clear fluid
   iii. Coarsening and thickening of the skin

3. Individual has been adherent with the medication

4. Individual has not developed any or significant adverse drug effects that may exclude continued use

Renewal duration: 30 gm tube for 30 days only

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Atopic dermatitis, also known as atopic eczema, is a chronic inflammatory disease that results in cracked, dry, itchy or oozing skin. Eczema is a group of chronic skin diseases that involve inflammation and cause itchy, irritated bumps, crusts and scales on the skin. It usually begins in childhood, with most patients having a first episode before the age of five. Symptoms may improve and worsen unpredictably. Inflammation and scratching eventually can thicken and toughen the skin. According to the National Eczema Association, about 11% of American children have eczema and most will continue to have symptoms into adulthood. Topical drug treatments for eczema include topical steroids, such as betamethasone and fluocinolone, calcineurin inhibitors, such as Protopic (tacrolimus ointment, generic) and Elidel (pimecrolimus), and topical phosphodiesterase inhibitor such as Eucrisa (crisaborole).

The American Academy of Dermatology (AAD) 2014 guidelines for the care and management of atopic dermatitis recommend topical corticosteroids for patients with atopic dermatitis who have failed to respond to standard non-pharmacologic therapy. The AAD also recommends the use of topical calcineurin inhibitors (tacrolimus, pimecrolimus) in patients who have failed to respond to, or who are not candidates for topical corticosteroid treatment. Eucrisa (crisaborole) is not included in the guideline.

Pimecrolimus (generic Elidel) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

ELIDEL® (pimecrolimus) cream
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Tacrolimus (generic Protopic) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable. Both 0.03% & 0.1% strengths are indicated for adults, and only the 0.03% is indicated for children aged 2 to 15 years.

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

The diagnosis of atopic dermatitis is based on clinical symptoms. There is no optimal long-term maintenance treatment and there is no known cure. In general, treatment involves elimination of exacerbating factors, restoring the skin's barrier function, hydrating the skin and use of topical anti-inflammatory agents. Patients with atopic dermatitis should avoid exacerbating factors including excessive bathing, low humidity environments, emotional stress, xerosis, and exposure to detergents. Thick creams with low water content or ointments which have zero water content protect against xerosis and should be utilized. Antihistamines are utilized as an adjunct in patients with atopic dermatitis to control pruritus and eye irritation. Sedating antihistamines such as diphenhydramine or hydroxyzine appear to be more effective than non-sedating agents.

Topical corticosteroids (TCS), low to high potency, are the standard of care. The strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. Selection of a product should also consider the degree of absorption through the skin and the potential for systemic adverse effects which are directly dependent on the surface area of the skin involved, thickness of the skin, the use of occlusive dressing, and the potency of the corticosteroid preparation. Low-potency corticosteroids are recommended for maintenance therapy, whereas intermediate- and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time. Use of ultra-high-potency corticosteroids is recommended only for very short periods (1 to 2 weeks) and in non-facial non-skinfold areas. Do not prescribe potent fluorinated corticosteroids for use on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Definitions:

Diagnostic criteria for atopic dermatitis: (*Diagnosis requires the presence of at least **3** major & **3** minor criteria)*

Major criteria
Pruritus
Dermatitis affecting flexural surfaces in adults and the face and extensors in infants
Chronic or relapsing dermatitis
Personal or family history of cutaneous or respiratory atopy
Minor criteria
Features of the so-called "atopic facies"

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Facial pallor or erythema
Hypopigmented patches
Infraorbital darkening
Infraorbital folds or wrinkles
Cheilitis
Recurrent conjunctivitis
Anterior neck folds
Triggers of atopic dermatitis
Foods
Emotional factors
Environmental factors
Skin irritants such as wool, solvents and sweat
Complications of atopic dermatitis
Susceptibility to cutaneous viral and bacterial infections
Impaired cell-mediated immunity
Immediate skin-test reactivity
Raised serum IgE
Keratoconus
Anterior subcapsular cataracts
Others
Early age of onset
Dry skin
Ichthyosis
Hyperlinear palms
Keratosis pilaris (plugged hair follicles of proximal extremities)
Hand and foot dermatitis
Nipple eczema

White dermatographism
Perifollicular accentuation

Adapted from: Hanifin JM, Rajka G, Acta Dermatol Venereol 1980; 92(Suppl):44.

Relative Potency of Topical Corticosteroids:

Potency group	Corticosteroid	Trade names (United States)	Available strength(s), percent (except as noted)	Vehicle type/form
Super-high potency	Betamethasone dipropionate, augmented	Diprolene	0.05	Ointment, optimized
		Diprolene	0.05	Lotion
		Diprolene	0.05	Gel
	Clobetasol propionate	Temovate	0.05	Ointment
		Temovate	0.05	Cream
		Temovate E	0.05	Cream, emollient base
		Temovate	0.05	Gel
		Clobex	0.05	Lotion
		Olux-E	0.05	Foam aerosol
		Olux	0.05	Foam aerosol (scalp)
		Clobex	0.05	Shampoo
		Temovate, Cormax	0.05	Solution (scalp)
		Clobex	0.05	Spray aerosol
	Diflucortolone valerate (not available in United States)	Nerisone Forte (United Kingdom, others)	0.3	Ointment, oily cream
	Fluocinonide	Vanos	0.1	Cream
	Flurandrenolide	Cordran	4 mcg/cm^2	Tape (roll)
	Halobetasol propionate	Ultravate	0.05	Ointment
		Ultravate	0.05	Cream
		Ultravate	0.05	Lotion
High potency	Amcinonide	Cyclocort¶, Amcort¶	0.1	Ointment
	Betamethasone dipropionate	Diprosone	0.05	Ointment
		Diprolene AF	0.05	Cream, augmented formulation (AF)
	Desoximetasone	Topicort	0.25	Ointment
		Topicort	0.25	Cream
		Topicort	0.05	Gel
	Diflorasone diacetate	ApexiCon¶, Florone¶	0.05	Ointment
		ApexiCon E	0.05	Cream, emollient
	Fluocinonide	Lidex¶	0.05	Ointment
		Lidex¶	0.05	Gel
		Lidex¶	0.05	Cream anhydrous
		Lidex¶	0.05	Solution
	Halcinonide	Halog	0.1	Ointment
		Halog	0.1	Cream

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	Amcinonide	Cyclocort¶, Amcort¶	0.1	Cream
		Amcort¶	0.1	Lotion
	Betamethasone dipropionate	Diprosone	0.05	Cream, hydrophilic emollient
	Betamethasone valerate	Valisone¶	0.1	Ointment
		Luxiq	0.12	Foam
	Desoximetasone	Topicort LP	0.05	Cream
	Diflorasone diacetate	Florone¶	0.05	Cream
	Diflucortolone valerate (not available in United States)	Nerisone (Canada, United Kingdom, others)	0.1	Cream, oily cream, ointment
	Fluocinonide	Lidex-E¶	0.05	Cream aqueous emollient
	Fluticasone propionate	Cutivate	0.005	Ointment
	Mometasone furoate	Elocon	0.1	Ointment
	Triamcinolone acetonide	Kenalog¶	0.5	Ointment
		Triderm, Aristocort HP¶	0.5	Cream
Medium potency	Betamethasone dipropionate	Sernivo	0.05	Spray
	Clocortolone pivalate	Cloderm	0.1	Cream
	Fluocinolone acetonide	Synalar¶	0.025	Ointment
	Flurandrenolide	Cordran	0.05	Ointment
	Hydrocortisone valerate	Westcort	0.2	Ointment
	Mometasone furoate	Elocon	0.1	Cream
		Elocon	0.1	Lotion
		Elocon¶	0.1	Solution
	Triamcinolone acetonide	Kenalog¶	0.1	Cream Ointment Aerosol spray
		Kenalog¶	0.1	
		Kenalog	0.2 mg per 2 second spray	
Lower-mid potency	Betamethasone dipropionate	Diprosone	0.05	Lotion
	Betamethasone valerate	Beta-Val, Valisone¶	0.1	Cream
	Desonide	Desowen, Tridesilon¶	0.05	Ointment
		Desonate	0.05	Gel
	Fluocinolone acetonide	Synalar¶	0.025	Cream
	Flurandrenolide	Cordran	0.05	Cream
		Cordran	0.05	Lotion
	Fluticasone propionate	Cutivate	0.05	Cream
		Cutivate	0.05	Lotion
		Locoid	0.1	Ointment

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	Hydrocortisone butyrate	Locoid, Locoid Lipocream	0.1	Cream
		Cortizone 10 maximum	0.1	Lotion, spray
		Locoid	0.1	Lotion
		Locoid	0.1	Solution
	Hydrocortisone probutate	Pandel	0.1	Cream
	Hydrocortisone valerate	Westcort¶	0.2	Cream
	Prednicarbate	Dermatop	0.1	Cream, emollient
		Dermatop	0.1	Ointment
	Triamcinolone acetonide	Kenalog¶	0.1	Lotion
		Kenalog¶	0.025	Ointment

Resources:

Elidel (pimecrolimus) 1% cream product information, revised by Bausch Health US, LLC. 09-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 17, 2021.

Eucrisa (crisaborole) 2% ointment product information, revised by Pfizer Laboratories Div Pfizer Inc. 04-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 17, 2021.

Pimecrolimus 1% cream product information, revised by Actavis Pharma, Inc. 05-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 17, 2021.

Protopic (tacrolimus) 0.03% & 0.1% ointment, product information, revised by Leo Pharma Inc. 02-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 17, 2021.

Tacrolimus 0.03% & 0.1% ointment, product information, revised by E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. 09-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 17, 2021.

Weston WL, Howe W. Atopic dermatitis (eczema): Pathogenesis, clinical manifestation, and diagnosis. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated July 22, 2021. Accessed December 17, 2021.

Weston WL, Howe W. Overview of dermatitis (eczema). In: UpToDate, Dellavalle RP, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated December 30, 2019. Accessed December 17, 2021.

Weston WL, Howe W. Treatment of dermatitis (eczema). In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated December 08, 2021. Accessed December 17, 2021.

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Berger TG. Evaluation and management of severe refractory atopic dermatitis (eczema) in adults. In: UpToDate, Fowler J, Levy ML, Dellavalle RP, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated March 18, 2021. Accessed December 17, 2021.

Spergel JM, Lio PA. Management of severe atopic dermatitis (eczema) in children. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated August 09, 2021. Accessed December 17, 2021.