PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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EUCRISA™ (crisaborole) ointment
ELIDEL® (pimecrolimus) cream
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) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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

Eucrisa (crisaborole) ointment

Criteria:

- **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** who has failure, contraindication (i.e., treatment of face or groin) or intolerance to **at least 2** of the low to medium potency brand or available generic corticosteroids (strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. See Definition section)

     b. **2 years to 17 years of age** who has

        i. Failure, contraindication (i.e., treatment of face or groin) or intolerance to **at least 2** of the low to medium potency brand or available 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 or intolerance to both topical tacrolimus and topical pimecrolimus

     c. **18 years of age or older** who has
        i. Failure, contraindication (i.e., treatment of face or groin) or intolerance to **at least 2** of the medium to high potency brand or available 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 or intolerance to both topical tacrolimus and topical pimecrolimus

  4. There are **NO** contraindications.
     a. Contraindications include:
        i. Known hypersensitivity to the medication or any component of its formulation

  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 contraindications that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section

Renewal duration: 60 gm tube for 30 days only

Elidel (pimecrolimus) cream
Protopic (tacrolimus) ointment

Criteria:

- **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 or intolerance to:
    a. **For brand Elidel (pimecrolimus) 1% cream:** generic pimecrolimus 1% topical cream **OR** tacrolimus 0.03% topical cream (brand **or** generic) **OR** Eucrisa (crisaborole) 2% ointment in a non-immunocompromised individual 2 years of age or older

b. **For brand Protopic (tacrolimus) 0.03% ointment:** generic tacrolimus 0.03% topical ointment **OR** Eucrisa (crisaborole) 2% ointment in a non-immunocompromised individual 2 years of age or older

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

5. Individual has failure, contraindication 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 diproprionate, augmented) 0.05% ointment or cream
    c. Betamethasone diproprionate 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. Vanos (fluocinonide) 0.1% cream
    k. Fluocinonide 0.05% ointment or cream
    l. Cordran SP (flurandrenolide) 0.05% cream
    m. Cutivate Fluticasone proprionate 0.005% ointment
    n. Cutivate Fluticasone proprionate 0.05% cream
    o. Halog (halcinonide) 0.1% ointment or cream
    p. Ultravate (halobetasol proprionate) 0.05% ointment or cream
    q. Elocon (mometasone furoate) 0.1% cream
    r. Dermatop (prednicarbate) 0.1% ointment or cream
    s. Triamcinolone acetonide 0.5% ointment or cream
    t. Triamcinolone acetonide 0.1% ointment or cream

6. There are **NO** contraindications.
    a. Contraindications include:
        i. Known hypersensitivity to the medication or any component of its formulation

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 contraindications or other significant level 4 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section

Renewal duration: 30 gm tube for 30 days only

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 (caisaborole).

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.

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) ointment
ELIDEL® (pimecrolimus) cream
PROTOPIC® (tacrolimus) ointment

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"
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	Vehicle type/form	Trade names (United States)	Available strength(s), percent

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

				(except as noted)
Super-high potency	Betamethasone dipropionate, augmented	Ointment, optimized	Diprolene	0.05
		Lotion	Diprolene	0.05
		Gel	Diprolene	0.05
	Clobetasol propionate	Ointment	Temovate	0.05
		Cream	Temovate	0.05
		Cream, emollient base	Temovate E	0.05
		Gel	Temovate	0.05
		Lotion	Clobex	0.05
		Foam aerosol	Olux-E	0.05
		Foam aerosol (scalp)	Olux	0.05
		Shampoo	Clobex	0.05
		Solution (scalp)	Temovate, Cormax	0.05
		Spray aerosol	Clobex	0.05
	Diflucortolone valerate (not available in United States)	Ointment, oily cream	Nerisone Forte (United Kingdom, others)	0.3
	Fluocinonide	Cream	Vanos	0.1
	Flurandrenolide	Tape (roll)	Cordran	4 mcg/cm^2
	Halobetasol propionate	Ointment	Ultravate	0.05
		Cream	Ultravate	0.05
		Lotion	Ultravate	0.05
High potency	Amcinonide	Ointment	Cyclocort¶, Amcort¶	0.1
	Betamethasone dipropionate	Ointment	Diprosone	0.05
		Cream, augmented formulation (AF)	Diprolene AF	0.05
	Desoximetasone	Ointment	Topicort	0.25
		Cream	Topicort	0.25
		Gel	Topicort	0.05
	Diflorasone diacetate	Ointment	ApexiCon¶, Florone¶	0.05
		Cream, emollient	ApexiCon E	0.05
	Fluocinonide	Ointment	Lidex¶	0.05
		Gel	Lidex¶	0.05
		Cream anhydrous	Lidex¶	0.05
		Solution	Lidex¶	0.05
	Halcinonide	Ointment	Halog	0.1
		Cream	Halog	0.1
	Amcinonide	Cream	Cyclocort¶, Amcort¶	0.1
		Lotion	Amcort¶	0.1
	Betamethasone dipropionate	Cream, hydrophilic emollient	Diprosone	0.05
	Betamethasone valerate	Ointment	Valisone¶	0.1
		Foam	Luxiq	0.12
	Desoximetasone	Cream	Topicort LP	0.05
	Diflorasone diacetate	Cream	Florone¶	0.05

EUCRISA™ (crisaborole) ointment
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PROTOPIC® (tacrolimus) ointment

	Diflucortolone valerate (not available in United States)	Cream, oily cream, ointment	Nerisone (Canada, United Kingdom, others)	0.1
	Fluocinonide	Cream aqueous emollient	Lidex-E¶	0.05
	Fluticasone propionate	Ointment	Cutivate	0.005
	Mometasone furoate	Ointment	Elocon	0.1
	Triamcinolone acetonide	Ointment	Kenalog¶	0.5
		Cream	Triderm, Aristocort HP¶	0.5
Medium potency	Betamethasone dipropionate	Spray	Sernivo	0.05
	Clocortolone pivalate	Cream	Cloderm	0.1
	Fluocinolone acetonide	Ointment	Synalar¶	0.025
	Flurandrenolide	Ointment	Cordran	0.05
	Hydrocortisone valerate	Ointment	Westcort	0.2
	Mometasone furoate	Cream	Elocon	0.1
		Lotion	Elocon	0.1
		Solution	Elocon¶	0.1
	Triamcinolone acetonide	Cream	Kenalog¶	0.1
		Ointment	Kenalog¶	0.1
		Aerosol spray	Kenalog	0.2 mg per 2 second spray
Lower-mid potency	Betamethasone dipropionate	Lotion	Diprosone	0.05
	Betamethasone valerate	Cream	Beta-Val, Valisone¶	0.1
	Desonide	Ointment	DesOwen, Tridesilon¶	0.05
		Gel	Desonate	0.05
	Fluocinolone acetonide	Cream	Synalar¶	0.025
	Flurandrenolide	Cream	Cordran	0.05
		Lotion	Cordran	0.05
	Fluticasone propionate	Cream	Cutivate	0.05
		Lotion	Cutivate	0.05
	Hydrocortisone butyrate	Ointment	Locoid	0.1
		Cream	Locoid, Locoid Lipocream	0.1
		Lotion, spray	Cortizone 10 maximum	0.1
		Lotion	Locoid	0.1
		Solution	Locoid	0.1
	Hydrocortisone probutate	Cream	Pandel	0.1
	Hydrocortisone valerate	Cream	Westcort¶	0.2

EUCRISA™ (crisaborole) ointment
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	Prednicarbate	Cream, emollient	Dermatop	0.1
		Ointment	Dermatop	0.1
	Triamcinolone acetonide	Lotion	Kenalog¶	0.1
		Ointment	Kenalog¶	0.025

Resources:

Elidel (pimecrolimus) 1% cream product information, revised by Bausch Health US, LLC. 09-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 11, 2021.

Eucrisa (crisaborole) 2% ointment product information, revised by Pfizer Laboratories Div Pfizer Inc. 03-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 11, 2021.

Pimecrolimus 1% cream product information, revised by Actavis Pharma, Inc. 05-2018, at DailyMed http://dailymed.nlm.nih.gov accessed January 11, 2021.

Protopic (tacrolimus) 0.03% & 0.1% ointment, product information, revised by Leo Pharma Inc. 04-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 11, 2021.

Tacrolimus 0.03% & 0.1% ointment, product information, revised by E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. 09-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 11, 2021.

Weston WL, Howe W. Overview of dermatitis (eczema). In: UpToDate, Dellavalle RP, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 11, 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. Accessed on January 11, 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. Accessed on January 11, 2021.

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; 71:116-32. Accessed February 13, 2017. Re-reviewed January 12, 2021.