PHARMACY COVERAGE GUIDELINE

EUCRISA™ (crisaborole) ointment
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Eucrisa (crisaborole) 2% ointment and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual has a confirmed diagnosis of mild to moderate atopic dermatitis
3. Individual is **ONE** of the following:
    a. **3 months of age or older** with atopic dermatitis involving the face, eyelids, neck, genitalia, or intertriginous areas

b. **3 months to 2 years of age** atopic dermatitis involving non-facial non-skinfold areas who has failure, contraindication per FDA label, intolerance, or is not a candidate for **at least 2** low to medium potency corticosteroids (brand or generic, strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. See Definitions section)

c. **3 years of age or older** with atopic dermatitis involving non-facial non-skinfold areas who has failure, contraindication per FDA label, intolerance, or is not a candidate for trial of **BOTH** of the following:
   i. **At least 1** low to medium potency or medium to high potency corticosteroids (brand or generic, strength is selected based on severity, duration of treatment, location of exacerbation, and age of patient. See Definitions section)
   ii. **At least 1** calcineurin inhibitor (topical tacrolimus or topical pimecrolimus)

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

Initial approval duration: 60 gm tube for 30 days only

- **Criteria for continuation of coverage (renewal request):** Eucrisa (crisaborole) 2% ointment and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

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 defined as continues to have the following:
   a. Red, scaly, itchy and crusted bumps
   b. Swelling, cracking, "weeping" clear fluid
   c. Coarsening and thickening of the skin

3. Individual has been adherent with the medication

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

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

Renewal duration: 12 months

- 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.

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:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Atopic Dermatitis Therapies:

Topical corticosteroids (TCS):

- Low-potency corticosteroids are recommended for maintenance therapy
- Intermediate and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time
- Ultra-high-potency corticosteroids should be used only for very short periods (1-2 weeks) and in non-facial non-skinfold areas.
- Do not use potent fluorinated corticosteroids on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Topical calcineurin inhibitors (TCI):

- Tacrolimus ointment (Protopic and generics) is indicated as second-line therapy for moderate to severe atopic dermatitis
- Pimecrolimus cream (Elidel and generics) is indicated as second line therapy for mild to moderate atopic dermatitis

Topical phosphodiesterase 4 (PDE-4) inhibitor:

- Eucrisa (crisaborole) ointment is indicated for treatment of mild to moderate atopic dermatitis

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.

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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
	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
	Hydrocortisone butyrate	Locoid	0.1	Ointment
		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:

Eucrisa (crisaborole) 2% ointment product information, revised by Pfizer Laboratories Div Pfizer Inc. 01-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 25, 2024.

Paller AS, Butala S, 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. Literature current through October 2024. Topic last updated November 11, 2024. Accessed November 27, 2024.

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. Literature current through October 2024. Topic last updated March 01, 2023. Accessed November 27, 2024.

Lio PA, Gonzalez ME. Management of severe refractory atopic dermatitis (eczema) in children. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through October 2024. Topic last updated September 20, 2024. Accessed November 27, 2024.