BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/15/18**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

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 (cont.)

Eucrisa (crisaborole)

Medication class:
Dermatologicals - Phosphodiesterase 4 (PDE4) Inhibitors

FDA-approved indication(s):
- For the topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

Recommended Dose:
- Apply a thin layer twice daily to affected areas.
- For topical use only.
- Not for ophthalmic, oral, or intravaginal use.

Maximum dosage
- There is no well-established maximum dose for the approved indication according to the prescribing information.

Available Dosage Forms:
- Ointment, 2%

Warnings and Precautions:
- Hypersensitivity reactions: If signs and symptoms of hypersensitivity occur, discontinue immediately and initiate appropriate therapy.

Criteria:

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

1. Prescriber is a Dermatologist
2. Individual is 2 years of age or older
3. A confirmed diagnosis of mild to moderate atopic dermatitis
4. Individual has failure, contraindication or intolerance to **Elidel (pimecrolimus) topical cream**
5. Individual has failure, contraindication or intolerance to **tacrolimus (generic Protopic) topical ointment**
6. Individual has failure, contraindication (treatment of face or groin) or intolerance to **at least 2** of the medium to high potency preferred step therapy agents:
   - Alclometasone
   - Amclinonide

- Augmented betamethasone
- Betamethasone
- Calcipotriene-betamethasone
- Clobetasol
- Clocortolone
- Desonide
- Desoximetasone
- Diflirasone
- Fluocinolone
- Fluocinonide
- Flurandrenolide
- Fluticasone
- Halog
- Halobetasol
- Hydrocortisone
- Mometasone
- Pramoxine-HC
- Prednicarbate
- Triamcinolone

7. There are **NO** contraindications.
    - Contraindications include:
        - 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) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to consult Dermatologist

2. Individual's condition has not worsened while on therapy
    - Worsening is defined as:
        - Red, scaly, itchy and crusted bumps
        - Seelling, cracking, "weeping" clear fluid
        - 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
    - Hypersensitivity reactions
    - Urticaria

5. There are no significant interacting drugs

Renewal duration: 60 gm tube for 30 days only

Elidel (pimecrolimus)

Medication class:
Dermatologicals - Immunosuppressive Agent

FDA-approved indication(s):
- 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.

Recommended Dose:
- Apply a thin layer to the affected skin twice daily.
- If signs and symptoms persist beyond 6 weeks, patients should be re-examined.
- Continuous long-term use should be avoided.
- Avoid use with occlusive dressings.

Maximum dosage
- There is no well-established maximum dose for the approved indication according to the prescribing information.

Available Dosage Forms:
- Cream, 1%

Warnings and Precautions:
- Should not be used in immunocompromised adults and children, including patients on systemic immunosuppressive medications.
- Avoid treatment on malignant or pre-malignant skin conditions, as these can present as dermatitis.
- Should not be used in patients with Netherton's Syndrome or skin diseases with a potential for increased systemic absorption.

Protopic (tacrolimus)

Medication class:
Dermatologicals - Immunosuppressive Agent

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

FDA-approved indication(s):

- Protopic Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, 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.

Recommended Dose:

- Apply a thin layer to the affected skin twice daily. The minimum amount should be rubbed in gently and completely to control signs and symptoms of atopic dermatitis.
- If signs and symptoms (eg, itch, rash, redness) do not improve within 6 weeks, patients should be reexamined to confirm the diagnosis of atopic dermatitis. Continuous long-term use of topical calcineurin inhibitors, including tacrolimus ointment, should be avoided, and application should be limited to areas of involvement with atopic dermatitis.
- Stop using when signs and symptoms of atopic dermatitis resolve.

Maximum dosage

- There is no well-established maximum dose for the approved indication according to the prescribing information.

Available Dosage Forms:

- Ointment, 0.03%, 0.1%

Warnings and Precautions:

- Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including Protopic Ointment.
- Continuous long-term use in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis.
- Protopic Ointment is not indicated for use in children less than 2 years of age. Only 0.03% Protopic Ointment is indicated for use in children 2-15 years of age.

Criteria:

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

  1. Prescriber is a Dermatologist

  2. **For Elidel (pimecrolimus)**: A confirmed diagnosis of mild to moderate atopic dermatitis
     For Protopic (tacrolimus): A confirmed diagnosis of moderate to severe atopic dermatitis

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

3. Individual is **EITHER** a non-immunocompromised adult **OR** child 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable

4. **For Protopic**: Individual has failure, contraindication or intolerance to **tacrolimus (generic Protopic) topical ointment**

5. Individual has failure, contraindication or intolerance to **at least 2** of the preferred medium to high potency topical corticosteroids:
    - Alclometasone
    - Amclinonide
    - Augmented betamethasone
    - Betamethasone
    - Calcipotriene-betamethasone
    - Clobetasol
    - Clocortolone
    - Desonide
    - Desoximetasone
    - Diflirasone
    - Fluocinolone
    - Fluocinonide
    - Flurandrenolide
    - Fluticasone
    - Halog
    - Halobetasol
    - Hydrocortisone
    - Mometasone
    - Pramoxine-HC
    - Prednicarbate
    - Triamcinolone

6. There are **NO** contraindications.
    - Contraindications include:
        - 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) and Protopic (tacrolimus) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to consult the Dermatologist

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

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

- Worsening is defined as:
  - Red, scaly, itchy and crusted bumps
  - Seelling, cracking, "weeping" clear fluid
  - 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
   - Contraindications or adverse effect:
     - Signs and symptoms may include:
       - Hypersensitivity reactions
       - Urticaria

5. There are no significant interacting drugs

Renewal duration: 30 gm tube for 30 days only

Resources:

Eucrisa. Package Insert. Revised by manufacturer 10/2017. Accessed 2-1-18.

Elidel. Package Insert. Revised by manufacturer 12/2017. Accessed 2-1-18.

Protopic. Package Insert. Revised by manufacturer 7/2017. Accessed 2-1-18.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.