Clinical Policy: Topical Agents: Immunomodulators

Reference Number: OH.PHAR.PPA.93
Effective Date: 01/01/2020 Revision Log
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

TOPICAL IMMUNOMODULATORS

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PIMECROLIMUS (generic of Elidel®) * PROTOPIC (tacrolimus)*	EUCRISA™ (crisaborole)* PIMECROLIMUS (generic of Elidel®) * [All other Labelers] TACROLIMUS (generic of Protopic®) *

* Pimecrolimus and tacrolimus have age restriction of 2 years or older

FDA approved indication(s)

Elidel cream is indicated for 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.

Eucrisa is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

Protopic ointment is indicated for 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Topical Agents: Immunomodulators are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Diagnosis of atopic dermatitis;
2. If request is for Eucrisa®, pimecrolimus (Elidel®), or tacrolimus (Protopic®) 0.03%, age ≥ 2 years;
3. If request is for tacrolimus (Protopic®) 0.1%, age ≥ 16 years;
4. If request is for a step therapy medication, member meets the following:
   a. Failure of two topical corticosteroids, each for ≥ 30 days, unless member meets one of the following (i, ii, iii, or iv):

i. Topical corticosteroids are inadvisable due to potential risks;
ii. Allergy to medications not requiring prior approval;
iii. Contraindication to or drug interaction with medications not requiring prior approval;
iv. History of unacceptable/toxic side effects to medications not requiring prior approval;

5. If request is for a non-preferred medication, failure of preferred medications, including a trial of ≥ 30 days of the preferred brand, unless member meets one of the following (a, b, or c):
a. Allergy to medications not requiring prior approval;
b. Contraindication to or drug interaction with medications not requiring prior approval;
c. History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Very High Potency		
augmented betamethasone 0.05% (Diprolene® AF) ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive weeks
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		
High Potency		
augmented betamethasone 0.05% (Diprolene® AF) cream, lotion	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency		
desoximetasone 0.05% (Topicort ®) cream, ointment, gel	Apply topically to the affected area(s) BID	Should not be used for longer than 3 consecutive months
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		

Topical Calcineurin Inhibitors		
Tacrolimus (Protopic®) 0.03% or 0.1% ointment	Apply a thin layer to affected area twice daily. Age 2-15 years, use 0.03% ointment only.	Limit use to affected areas. Discontinue when symptoms have cleared.

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed warnings

- Contraindication(s): hypersensitivity to the active ingredient or any other component of the product
- Boxed warning(s):
  - Pimecrolimus (Elidel®) and tacrolimus (Protopic®): malignancy
  - Crisaborole (Eucrisa®): none reported

Appendix D: General Information

- On March 10, 2005, the FDA issued a public health advisory about a potential cancer risk from Elidel. The FDA recommends that Elidel should be used second-line, avoided in children below the age of 2, and used in minimum amounts intermittently to control symptoms. Black box warning and Medication Guide for patients have been instituted, as recommended by the FDA.
- A Consensus Conference on Atopic Dermatitis sponsored by the American Academy of Dermatology recommended that topical immunomodulator agents should be reserved for second line therapy in patients who fail standard interventions, including low to mid potency topical corticosteroids.

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Elidel	A thin layer topically to affected skin BID	30 gm tube/month
Protopic	A thin layer topically to affected skin BID	30 gm tube/month
Eucrisa	A thin layer topically to affected skin BID	N/A

V. Product Availability

Drug	Availability
Elidel	Cream: 1%
Protopic	Ointment: 0.03%, 0.1%
Eucrisa	Ointment: 2%

VI. References

1. Elidel Package Insert. Bridgewater, NJ: Valeant Pharmaceuticals North America, LLC, December 2017. Available at http://www.elidel-us.com. Accessed November 5, 2018.
2. Protopic Package Insert. Madison, NJ: LEO Pharma Inc., December 2017. Available at https://www.protopic.com. Accessed November 5, 2018.

3. 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 Aug; 71(1):116-32.
4. Eucrisa Prescribing Information. New York: NY: Pfizer Labs, Division of Pfizer, Inc.; December 2018. Available at: www.eucrisa.com. Accessed February 8, 2019.
5. Paller AS, Tom WL, Lebwohl MG, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. J Am Acad Dermatol. 2016;75:3:494-503.
6. Wong JTY, Tsuyuki RT, Cresswell-Melville A, et al. Guidelines for the management of atopic dermatitis (eczema) for pharmacists. Can Pharm J (Ott). May 2017;150(5):285-297.
7. Ference JD and Last AR. Choosing topical corticosteroids. American Family Physician Journal. January 2009; 79(2):135-140.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.