Effective Date: 10/01/2015
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C8268-A

Atopic Dermatitis (Elidel-Protopic-Eucrisa)

PRODUCTS AFFECTED

ELIDEL (pimecrolimus), EUCRISA (crisaborole), PROTOPIC (tacrolimus), pimecrolimus, tacrolimus topical

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Atopic Dermatitis, intertriginous psoriasis, vulvar lichen sclerosis, oral lichen planus, pyoderma gangrenosum

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. ATOPIC DERMATITIS (FOR ALL PRODUCTS):
   1. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), intolerance, or contraindication (e.g., areas involving the face,neck or intertriginous areas) to at least TWO formulary medium or high potency topicalsteroids (see Appendix)

AND

2. ELIDEL/EUCRISA ONLY: Documentation of trial and failure (minimum of 2-weeks) oftopical tacrolimus (WHEN AGE APPROPRIATE), unless contraindicated or clinically significant adverse effects are experienced

B. INTERTRIGINOUS PSORIASIS:
   1. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), intolerance, or contraindication to at least TWO formulary lowpotency topical steroids (see Appendix)

C. VULVAR LICHEN SCLEROSUS:
   1. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), intolerance, or contraindication to at least TWO formulary veryhigh potency topical steroids (see Appendix)

D. ORAL LICHEN PLANUS:
   1. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), intolerance, or contraindication (e.g., areas involving the face,neck, or intertriginous areas) to at least TWO formulary topical steroids (see Appendix)

E. PYODERMA GANGRENOSUM:
   1. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), intolerance, or contraindication (e.g., areas involving the face,neck or intertriginous areas) to at least TWO formulary topical steroids (see Appendix)

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (FOR ALL PRODUCTS):
   1. Documentation that member's condition has improved based upon the prescriber's assessment of disease control and clinical improvements while on therapy (e.g., reduction of affected BSA, improvements in severity of eczematous lesions, decrease in pruritus severity)
      AND
   2. Member's condition has not worsened while on therapy. Worsening may be defined as: Red, scaly, itchy, and crusted bumps; swelling, cracking, "weeping" clear fluid; Coarsening and thickening of the skin

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

EUCRISA (crisaborole): 3 months of ageand older
PROTOPIC (tacrolimus) 0.1% ointment: 16 years of age or older
ELIDEL (pimecrolimus), PROTOPIC (tacrolimus) 0.03% ointment: 2 years of age and older

QUANTITY:

ELIDEL (pimecrolimus)- 60g/25 days
PROTOPIC (tacrolimus): 30g/30 days
EUCRISA (crisaborole): 60 gm per 30 days or 120 gm per 30 days when 5% or greater body surface area is affected.[provider must submit documentation to support higher 120gram approval]

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical.

DRUG CLASS:
Phosphodiesterase 4 (PDE 4) Inhibitors-Topical, Macrolide Immunosuppressants-Topical

FDA-APPROVED USES:
Elidel is indicated as **second-line therapy** for the short-term and noncontinuous 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.

Protopic (tacrolimus) is indicated as **second-line therapy** for the short-term and noncontinuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, [both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years], who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients3 months of age and older.

COMPENDIAL APPROVED OFF-LABELED USES:
PIMECROLIMUS & TACROLIMUS ONLY:
Intertriginous psoriasis, Vulvar lichen sclerosus, Oral lichenplanus.
TACROLIMUS ONLY: Pyodermagangrenosum

APPENDIX

APPENDIX:
Very High Potency
Betamethasone dipropionate (augmented)
Clobetasol
Diflorasone diacetate ointment
Halobetasol

High Potency
Amcinonide
Betamethasone dipropionate
Desoximetasone gel, ointment, or cream 0.25% or more
Diflorasone diacetate cream
Fluocinolone cream 0.2% or more
Fluocinonide
Halcinonide
Triamcinolone 0.5% or more

Medium Potency
Beclomethasone

Betamethasone benzoate
Betamethasone valerate
Hydrocortisone acetate
Clobetasone
Clocortolone
Desoximetasone cream less than 0.25%
Diflucortolone
Fluocinolone ointment or topical solution or cream less than 0.2%
Flurandrenolide 0.025% or more
Fluticasone
Hydrocortisone butyrate
Hydrocortisone valerate
Mometasone Prednicarbate
Triamcinolone less than 0.5%

Low Potency
Alclometasone
Desonide Dexamethasone
Flumethasone
Flurandrenolide less than 0.025%
Hydrocortisone base

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The American Academy of Dermatology guidelines for the care and management of atopic dermatitis recommend topical corticosteroids for patients with atopic dermatitis who have failed to respond to standard nonpharmacologic therapy. They also recommend 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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of ELIDEL (pimecrolimus), EUCRISA (crisaborole), and PROTOPIC (tacrolimus) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to pimecrolimus include history of hypersensitivity to pimecrolimus or any of the components of the cream. Contraindications to Eucrisa (crisaborole) include known hypersensitivity to crisaborole or any component of the formulation. Contraindications to Protopic (tacrolimus) include patients with a history of hypersensitivity to tacrolimus or any other component of the ointment.

OTHER SPECIAL CONSIDERATIONS:
Elidel (pimecrolimus) and Protopic (tacrolimus) both have a black box warning for malignancy (for example, skin and lymphoma). Continuous long-term use of any age and application to areas not involved with atopic dermatitis should be avoided. Use of Elidel should be limited to individuals aged 2 years or older. Protopic 0.1% is not indicated for use in children less than 16 years of age.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION

NA	

AVAILABLE DOSAGE FORMS:
Eucrisa OINT 2% Elidel CREA 1% Pimecrolimus CREA 1% Tacrolimus OINT 0.03% Protopic OINT 0.03% Protopic OINT 0.1% Tacrolimus OINT 0.1%, tacrolimus cream 0.1%

REFERENCES

1. Eucrisa Ointment 2% (crisaborole) [prescribing information]. New York, NY: Pfizer Labs; April 2020
2. Elidel (pimecrolimus) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
3. Protopic (tacrolimus) [prescribing information]. Madison, NJ: LEO Pharma Inc; February 2019.
4. 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. JAm Acad Dermatol. 2014; 71(1):116-32.
5. Eichenfield LF, Boguniewicz M, Simpson EL, et al. Translating Atopic Dermatitis
6. ManagementGuidelines Into Practice for Primary Care Providers. *Pediatrics.* 2015;136(3):554-565.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- FDA Approved Uses References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file