Effective Date: 1/1/2020
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 4/2023
Policy Number: C21052-A

Atopic Dermatitis (Elidel-Protopic-Eucrisa) IL Medicaid Only

PRODUCTS AFFECTED

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

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 (all products), Intertriginous Psoriasis, Vulvar Licen Sclerosus, Oral Lichen Planus, Pyoderma Gangrenosum, Vitiligo

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. Protopic (tacrolimus)/Elidel (pimecrolimus): 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 topical steroids

   OR

2. Eucrisa (crisaborole) ONLY: Documentation of trial and failure of ONE topical corticosteroid OR ONE topical calcineurin inhibitor

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

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

D. ORAL LICHEN PLANUS (PIMECROLIMUS & TACROLIMUS ONLY):
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 (TACROLIMUS ONLY):
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)

F. VITILIGO (PIMECROLIMUS & TACROLIMUS ONLY):
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. EUCRISA ONLY
1. Documentation that member meets initial criteria.

B. PIMECROLIMUS & TACROLIMUS ONLY [ALL INDICATIONS]:
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: 6 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Elidel (pimecrolimus) 1%: 2 years of age and older
Eucrisa (crisaborole) 2%: 3 months of age and older
Protopic (tacrolimus) 0.03% ointment: 2 years of age and older

Protopic (tacrolimus) 0.1% ointment: 16 years of age and older

QUANTITY:
Up to a 60-day supply per fill
Eucrisa: 300 grams per year

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

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
External, Topical

DRUG CLASS:
Phosphodiesterase 4 (PDE4) Inhibitors - Topical
Calcineurin-inhibitor Immunosuppressants - Topical

FDA-APPROVED USES:
Eucrisa (crisaborole) ointment: indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older

Protopic (tacrolimus): indicated as second-line therapy for the short-term and noncontinuous chronic treatment of moderate to severe atopic dermatitis in nonimmunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable

Elidel (pimecrolimus): indicated as second-line therapy for the short-term and noncontinuous chronic treatment of mild to moderate atopic dermatitis in nonimmunocompromised adults and children 2 years of age or older, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable

COMPENDIAL APPROVED OFF-LABELED USES:
PIMECROLIMUS & TACROLIMUS ONLY: Intertriginous psoriasis, Vulvar lichen sclerosus, Oral lichen planus, Vitiligo
TACROLIMUS ONLY: Pyoderma gangrenosum

APPENDIX

APPENDIX:

Very High Potency
Betamethasone dipropionate (augmented)
Clobetasol propionate
Halobetasol propionate

High Potency
Amcinonide
Betamethasone dipropionate
Desoximetasone gel, ointment, or cream 0.25% or more

Diflorasone diacetate cream
Fluocinonide
Halcinonide
Triamcinolone 0.5% or more

Medium Potency
Betamethasone valerate
Clocortolone
Desoximetasone cream less than 0.25%
Fluocinolone ointment or topical solution or cream less than 0.2%
Flurandrenolide 0.025% or more
Fluticasone
Hydrocortisone butyrate
Hydrocortisone valerate
Mometasone
Prednicarbate
Triamcinolone acetonide less than 0.5%

Low Potency
Alclometasone
Desonide
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.

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 and Protopic 0.03% 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%
Tacrolimus OINT 0.1%
Protopic OINT 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. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 4.1.2022, revised.
5. 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(1):116-32.
6. Eichenfield LF, Boguniewicz M, Simpson EL, et al. Translating Atopic Dermatitis Management Guidelines Into Practice for Primary Care Providers. Pediatrics. 2015;136(3):554-565.
7. Whitton, M. E., Pinart, M., Batchelor, J., Leonardi-Bee, J., González, U., Jiyad, Z., Eleftheriadou, V., & Ezzedine, K. (2015). Interventions for vitiligo. The Cochrane database of systematic reviews, (2), CD003263.
8. Arora, C. J., Rafiq, M., Shumack, S., & Gupta, M. (2020). The efficacy and safety of tacrolimus as mono- and adjunctive therapy for vitiligo: A systematic review of randomised clinical trials. *The Australasian journal of dermatology*, *61*(1), e1–e9. https://doi.org/10.1111/ajd.13096

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2/2022