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 Last Approval/Version: 04/2024
 Next Review Due By: 04/2025
 Policy Number: C21052-A

Atopic Dermatitis Agents (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, Psoriasis, Vulvar Lichen 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. FOR EUCRISA (crisaborole) ONLY:

1. Documentation of at least a 30-day trial and failure of ONE topical corticosteroid or ONE topical calcineurin inhibitor in the last 180 days.
OR

B. FOR ELIDEL (pimecrolimus) & PROTOPIC (tacrolimus):

1. Documented diagnosis of ONE of the following [DOCUMENTATION REQUIRED]:
 - a. Atopic dermatitis

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- b. Psoriasis (see Appendix)
 - c. Vulvar lichen sclerosus
 - d. Oral lichen planus
 - e. Pyoderma gangrenosum
 - f. Vitiligo
- AND
2. Documentation of prescriber baseline assessment of disease activity (e.g., affected BSA, severity of eczematous lesions, pruritus, etc.).
- AND
3. 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 of appropriate potency for the requested indication (see Appendix).

CONTINUATION OF THERAPY:

A. FOR EUCRISA (crisaborole) ONLY:

1. Documentation that member meets initial criteria.
- OR

B. FOR ALL OTHER 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, etc.).
- AND
2. Documentation member's condition has not worsened while on therapy (e.g., red, scaly, itchy, and crusted bumps; swelling, cracking, "weeping" clear fluid; Coarsening and thickening of the skin).
- AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity.

DURATION OF APPROVAL:

Initial authorization: 6 months

Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

EUCRISA (crisaborole): 3 months of age and older

PROTOPIC (tacrolimus) 0.1% ointment: 16 years of age or older

PROTOPIC (tacrolimus) 0.03% ointment: 2 years of age and older

ELIDEL (pimecrolimus) 1% cream: 2 years of age and older

QUANTITY:

Eucrisa: 300 grams per year

All other products: Up to a 60-day supply per fill

PLACE OF ADMINISTRATION:

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

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

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Drug and Biologic Coverage Criteria

Topical

DRUG CLASS:

Topical Phosphodiesterase-4 (PDE-4) Inhibitors

Topical Calcineurin Inhibitors

FDA-APPROVED USES:

Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

Protopic (tacrolimus) is 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) is 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: vulvar lichen sclerosus, inverse (intertriginous) psoriasis, dermatomyositis, vitiligo

TACROLIMUS: vulvar lichen sclerosus, acute cutaneous graft-versus-host disease (GVHD), chronic allergic contact dermatitis, dermatomyositis, geographic tongue, inverse (intertriginous) psoriasis

EUCRISA: none

APPENDIX

APPENDIX 1:

Atopic Dermatitis: Medium to high potency (dependent on severity)

Intertriginous Psoriasis: Low potency

Vulvar Lichen Sclerosus: Very high potency

Oral lichen planus: Medium to high potency

Pyoderma gangrenosum: High potency

APPENDIX 2:

Very High Potency

Betamethasone dipropionate (augmented)

Clobetasol propionate

Diflorasone diacetate ointment

Halobetasol propionate

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

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Betamethasone benzoate
Betamethasone valerate
Hydrocortisone acetate
Clobetasone
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
Dexamethasone
Flumethasone
Flurandrenolide less than 0.025%
Hydrocortisone base

APPENDIX 3:

Guidelines of care for the management of psoriasis and psoriatic arthritis (AAD 2009)

Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures (Joint AAD-NPF 2021)

Although not FDA approved for psoriasis, the topical calcineurin inhibitors tacrolimus and pimecrolimus are often used in the treatment of psoriasis. Both agents have demonstrated efficacy when used under occlusion, on facial and intertriginous psoriasis, and are used as steroid-sparing agents for prolonged (>4 weeks) use. The off-label combination of tacrolimus and 6% salicylic acid for 12 weeks may be used for the treatment of plaque psoriasis.

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 Elidel (pimecrolimus) include history of hypersensitivity to pimecrolimus or any of the components of the cream, use in immunocompromised adults and children including patients on systemic immunosuppressive medications, and patients with Netherton's Syndrome.

Contraindications to Eucrisa (crisaborole) include known hypersensitivity to crisaborole or any component of the formulation.

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Contraindications to Protopic (tacrolimus) include patients with a history of hypersensitivity to tacrolimus or any other component of the ointment, use in immunocompromised adults and children.

OTHER SPECIAL CONSIDERATIONS:

Elidel (pimecrolimus) and Protopic (tacrolimus) both have a black box warning for malignancy (e.g., skin and lymphoma). Continuous long-term use of any age and application to areas not involved with atopic dermatitis should be avoided.

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%

Tacrolimus OINT 0.1%

Protopic OINT 0.1%

REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 01/01/2024.
2. Illinois Medicaid Preferred Drug List, Effective January 1, 2024.
3. Eucrisa Ointment 2% (crisaborole) [prescribing information]. New York, NY: Pfizer Labs; April 2023.
4. Elidel (pimecrolimus) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September, 2020.
5. Protopic (tacrolimus) [prescribing information]. Madison, NJ: LEO Pharma Inc; February 2019.
6. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 4.1.2023
7. 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.
8. 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.
9. 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.

Drug and Biologic Coverage Criteria

10. 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 randomized 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- Notable revisions: Required Medical Information Age Restrictions Appendix Contraindications References	04/2024
ANNUAL REVIEW COMPLETED – Eucrisa lookback updated to match stipulated language.	Q2/2023
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4/2022
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2/2022

Medicaid Only