Original Effective Date: 10/01/2015
Current Effective Date: 06/13/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C8268-A

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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:

1. Documented diagnosis of ONE of the following [DOCUMENTATION REQUIRED]:
   a. Atopic dermatitis
   b. Psoriasis (see Appendix)
   c. Vulvar lichen sclerosus
   d. Oral lichen planus
   e. Pyoderma gangrenosum
   AND
2. Documentation that the member experienced an inadequate treatment response (minimum 2-week trial), serious side effects, 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)
   AND
3. Documentation of prescriber baseline assessment of disease activity (e.g., affected BSA, severity of eczematous lesions, pruritis, etc.)
   AND
4. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. 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, 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: 3 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
ELIDEL (pimecrolimus), PROTOPIC (tacrolimus) 0.03% ointment: 2 years of age and older

QUANTITY:

ELIDEL (pimecrolimus): formulary quantity limit 60g/30 days
PROTOPIC (tacrolimus): formulary quantity limit 30g/30 days
EUCRISA (crisaborole): 60g per 30 days or 120g per 30 days when 5% or greater body surface area is affected. [Provider must submit documentation to support greater than 120 gram 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 (pimecrolimus) 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 patients 3 months of age and older.

COMPENDIAL APPROVED OFF-LABELED USES:
Pimecrolimus & Tacrolimus ONLY: Intertriginous psoriasis, Vulvar lichen sclerosus, Oral lichen planus.
Tacrolimus ONLY: Pyoderma gangrenosum

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
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

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.
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. 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%

REFERENCES

1. Eucrisa Ointment 2% (crisaborole) [prescribing information]. New York, NY: Pfizer Labs; April 2023.
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 Management Guidelines Into Practice for Primary Care Providers. *Pediatrics.*2015;136(3):554-565.
6. Menter A, Korman N, Elmets C, et al. Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis. Section 3. Guidelines of Care for the Management and Treatment of Psoriasis with Topical therapies. J Am Acad Dermatol 2009; 60:643-59.
7. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021; 84:432.
8. Sidbury R, Alikhan A, Bercovitch L, Cohen DE, Darr JM, Drucker AM, Eichenfield LF, Frazer-Green L, Paller AS, Schwarzenberger K, Silverberg JI, Singh AM, Wu PA, Davis DMR, Guidelines of care for the management of atopic dermatitis in adults with topical therapies, Journal of the American Academy of Dermatology (2023), doi: https://doi.org/10.1016/j.jaad.2022.12.029.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Appendix References	Q2 2024
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation References	Q2 2023
REVISION-Notable revisions: FDA Approved Uses References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file