Clinical Policy: Topical Immunomodulators

Reference Number: CP.PMN.107
Effective Date: 09.01.06
Last Review Date: 02.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

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

Description

The following are topical immunomodulators requiring prior authorization: pimecrolimus (Elidel®) and tacrolimus (Protopic®).

FDA Approved Indication(s)

Topical immunomodulators are indicated as second-line therapy for the short-term and non-continuous chronic treatment of 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.

- Elidel cream is specifically indicated for mild to moderate disease in patients 2 years of age and older.
- Protopic ointment is specifically indicated for moderate to severe disease.

Limitation(s) of use: Protopic ointment and Elidel cream are not indicated for children younger than 2 years of age.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Protopic and Elidel/generics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis or Vitiligo (must meet all)**:**

1. Diagnosis of atopic dermatitis or vitiligo;
2. If request is for tacrolimus 0.03% ointment or pimecrolimus, member is ≥ 2 years of age;
3. If request is for tacrolimus 0.1% ointment, member is ≥ 16 years of age;
4. If request is for brand Protopic or Elidel, member must use generic topical tacrolimus or pimecrolimus, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Member meets one of the following (a, b, or c):
   a. Children and adolescents: Failure of 2 medium potency topical corticosteroids in the previous 6 months, unless all are contraindicated or clinically significant adverse effects are experienced;

b. Adults: Failure of 2 high or very high potency topical corticosteroids in the previous 6 months, unless all are contraindicated or clinically significant adverse effects are experienced;
c. Use on the face or skinfolds;

6. Request does not exceed health plan-approved quantity limit.*
**Refer to Health Plan PDL or formulary*

Approval duration:
HIM/ICHRA/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Plaque Psoriasis (off-label) (must meet all)**:**
1. Diagnosis of plaque psoriasis;
2. Age ≥ 2 years;
3. Prescribed for use on face or intertriginous areas (e.g., genitals, armpits, forearms, and groin);
4. If request is for brand Protopic or Elidel, member must use generic topical tacrolimus or pimecrolimus, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Request does not exceed health plan-approved quantity limit.*
**Refer to Health Plan PDL or formulary*

Approval duration:
HIM/ICHRA/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

2. Member is responding positively to therapy;
3. If request is for brand Protopic or Elidel, member must use generic topical tacrolimus or pimecrolimus, unless clinically significant adverse effects are experienced or both are contraindicated;
4. If request is for a dose increase, new dose does not exceed health plan-approved quantity limit.*
   **Refer to Health Plan PDL or formulary*

Approval duration:
HIM/Medicaid – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. 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 policies – CP.CPA.09 for commercial, HIM.PA.154for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key
AAD: American Academy of Dermatology
FDA: Food and Drug Administration
NPF: National Psoriasis Foundation

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
augmented betamethasone 0.05% (Diprolene®) gel	Apply topically to the affected area(s) BID	Should not be used for longer than 2 - 3 consecutive weeks
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon®Psorcon®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
augmented betamethasone 0.05% (Diprolene® AF, Diprolene®) cream, ointment, lotion		
diflorasone 0.05% (Apexicon®Psorcon ®) cream		
fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% cream, ointment		
desoximetasone 0.25% (Topicort®) cream, ointment		
desoximetasone 0.05% (Topicort ®) cream, gel		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% cream, ointment		

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): long-term safety of topical calcineurin inhibitors has not been established:

- Although a casual relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients with topical calcineurin inhibitors. Therefore:
  - Continuous long-term use of topical calcineurin inhibitors in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis
  - Not indicated for use in children less than 2 years of age
  - Only 0.03% Protopic Ointment is indicated for use in children 2-15 years of age (*Protopic only*)

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. Boxed 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.
- The 2021 American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) guidelines for the management and treatment of psoriasis with topical therapy recommendations:
  - 2.1 The off-label usage of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis for up to 8 weeks can be considered.
  - 2.2 The off-label use of pimecrolimus for inverse psoriasis for 4-8 weeks is recommended.
- The 2020 AAD and NPF guideline for the management and treatment of psoriasis in pediatric patients recommendations:
  - 11.1 Tacrolimus 0.1% ointment is recommended for off-label use as monotherapy for pediatric psoriasis of the face and genital region.

V. 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

VI. Product Availability

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

VII. References

1. Elidel Package Insert. Bridgewater, NJ: Valeant Pharmaceuticals North America, LLC, September 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=e4027e5a-0f9b-4070-b196-f60172f45c4c&type=pdf. Accessed November 7, 2025.
2. Protopic Package Insert. Madison, NJ: LEO Pharma Inc., June 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51218de3-dabc-4972-9c5b-750c8b1d8083. Accessed November 7, 2025.

Atopic Dermatitis

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. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1):e1-e20.

Plaque Psoriasis

5. 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(2):432-70.
6. Menter A, Cordoro K, Davis D, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol 2020;82:161-201.
7. Menter A, Korman NJ, Elmets CA, et al. From the Academy 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(4):642-659.
8. Brune A, Miller DW, Lin P, Cotrim-Russi D, Paller AS. Tacrolimus ointment is effective for psoriasis on the face and intertriginous areas in pediatric patients. Pediatr Dermatol. 2007;24(1):76-80.
9. Steele JA, Choi C and Kwong PC. Topical tacrolimus in the treatment of inverse psoriasis in children. J Am Acad Dermatol 2005;52(4):713-716.
10. Kalb RE, Bagel J, Korman NJ, et al. Treatment of intertriginous psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2009;60(1):120-124.

Reviews, Revisions, and Approvals	Date	P & T Approval Date
1Q 2022 annual review: added redirection to generic formulations; revised quantity limit to allow up to Health Plan-approved quantity limit as defined in the PDL/formulary; references reviewed and updated.	11.16.21	02.22
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less.	04.27.22	08.22

Reviews, Revisions, and Approvals	Date	P & T Approval Date
Added off-label indication for plaque psoriasis as supported by AAD-NPF guidelines. Template changes applied to other diagnoses/indications and continued therapy section.	09.06.22	11.22
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.17.22	02.23
1Q 2024 annual review: no significant changes; clarified trial and failure is "topical" corticosteroids; references reviewed and updated.	10.16.23	02.24
1Q 2025 annual review: no significant changes; for Appendix C, updated boxed warning section to align with Protopic PI; references reviewed and updated.	11.07.24	02.25
1Q 2026 annual review: no significant changes; references reviewed and updated.	11.07.25	02.26
For continued therapy, corrected typo by adding "exceed" for "new dose does not exceed health plan-approved quantity limit" criterion; added ICHRA line of business.	07.20.26	

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.