Clinical Policy: Topical Immunomodulators

Reference Number: CP.PMN.107
Effective Date: 09.01.06
Last Review Date: 02.18
Line of Business: 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)

Elidel cream is indicated for second‑line therapy for the short-term and non-continuous 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 ointment is indicated for second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe 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

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 (must meet all)**:**

1. Diagnosis of atopic dermatitis;
2. If request is for tacrolimus 0.03% ointment, member is ≥ 2 years of age;
3. If request is for tacrolimus 0.1% ointment, member is ≥ 16 years of age;
4. Member is immunocompetent;
5. Member must meet one of the following (a, b, or c):
   a. Children and adolescents: Failure of 2 medium potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all PDL topical corticosteroids;
   b. Adults: Failure of 2 high or very high potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all PDL topical corticosteroids;

c. Use on the face or skinfolds;

6. Request does not exceed a 30 gm tube per month.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed a 30 gm tube per month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy - CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

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 consecutive weeks
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks

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

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: 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. Black box 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.

V. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Elidel	A thin layer to affected skin twice daily	30 gm tube/month
Protopic	A thin layer to affected skin twice daily	30 gm tube/month

VI. Product Availability

Drug	Availability
Elidel	1% cream
Protopic	0.03% ointment, 0.1% ointment

VII. References

1. Elidel Package Insert. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC, June 2017. Available at http://www.elidel-us.com. Accessed November 24, 2017.
2. Protopic Package Insert. Madison, NJ: LEO Pharma Inc., November 2016. Available at https://www.protopic.com. Accessed November 24, 2017.
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.

Reviews, Revisions, and Approvals	Date	P & T Approval Date
Added Protopic to criteria document. Revised the description to create category language (formerly referred only to pimecrolimus). Added references for Protopic.	02.13	02.13
Updated reference section to reflect current literature search.	02.14	02.14
Updated reference section to reflect current literature search.	02.15	02.15
Converted into new policy template; Added that member must be immunocompetent; Added that topical steroid must have been trialed and failed in the last 6 months; Added that disease on the skinfolds could be approved without use of steroid to avoid skin atrophy; Updated reference section to reflect current literature search.	12.15	02.16
Converted to new integrated template; Updated literature search; Removed the following age requirement: Pimecrolimus 1%	11.16	02.17

Reviews, Revisions, and Approvals	Date	P & T Approval Date
cream ≥ 2 years of age, because age restrictions are not absolute contraindications per FDA labeling; added positive response to therapy requirement for re-authorization.		
1Q18 annual review: - Policy changed from CP.PPA to CP.PMN. - Changed authorization duration limits from 3/6 months to 6/12 months - Removed restriction against coverage for vitiligo - References reviewed and updated.	12.5.17	02.18

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.

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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.