Clinical Policy: Topical Immunomodulators

Reference Number: PA.CP.PMN.107
Effective Date: 09.01.06
Last Review Date: 01.19

Revision Log

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 (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness 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. Member meets one of the following (a, b, or c):
   a. Children and adolescents: Failure of a medium potency corticosteroid in the previous 6 months, unless contraindicated or clinically significant adverse effects are experienced;
   b. Adults: Failure of a high or very high potency corticosteroid in the previous 6 months, unless contraindicated or clinically significant adverse effects are experienced;
   c. Use on the face or skinfolds;
5. Request does not exceed a 30 gm tube per month.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to PA.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 or Vitiligo (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.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 - PA.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: Contraindications/Boxed warnings

- Contraindication(s): hypersensitivity to the active ingredient or any other component of the product
- Boxed warning(s): malignancy

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. 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 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, December 2017. Available at http://www.elidel-us.com. Accessed November 5, 2018.
2. Protopic Package Insert. Madison, NJ: LEO Pharma Inc., December 2017. Available at https://www.protopic.com. Accessed November 5, 2018.
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
1Q 2019 annual review: Policies combined (PA.CP.PMN.98) and (PA.CP.PMN.107); per previously approved policy PA.CP.PMN.98 – removed "Member is immunocompetent", added vitiligo with specific coverage criteria, added age limit for Elidel. References reviewed and updated.	01/19	