Clinical Policy: Pimecrolimus (Elidel)
Reference Number: CP.CPA.25
Effective Date: 11.16.16
Last Review Date: 08.17 Revision Log
Line of Business: Medicaid – Medi-Cal

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

Description
Pimecrolimus (Elidel®) is an immunosuppressant topical cream. It's mechanism of action is not known, but it has been shown to inhibit T cell activation by blocking transcription of cytokines. It also inhibits interleukin-2, interferon gamma, interleukin-4, and interleukin-10 cytokine synthesis in human T-cells. In addition, it prevents the release of inflammatory cytokines and mediators from mast cells after stimulation by antigens.

FDA approved indication
Elidel is indicated:

- For the treatment of 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.

Limitation of use: Elidel Cream, 1% is not indicated for use in children less 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 Centene Corporation® that Elidel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of mild to moderate atopic dermatitis (a form of eczema) or vitiligo;
2. Age ≥ 2 years;
3. Failure of TWO formulary medium to high potency topical corticosteroids unless member experiences clinically significant adverse effects or has contraindication(s) (i.e. areas involving the face, neck, and intertriginous areas);
4. Dose does not exceed 2 applications/day

Approval duration: Length of Benefit

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, Vitiligo (must meet all)**:**

1. Currently receiving medication via health plan benefit or member has previously met initial approval criteria;
2. Dose does not exceed 2 applications/day.

Approval duration: Length of Benefit

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

1. Currently receiving medication via health plan 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 diagnosis is NOT specifically 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.

B. Treatment of allergic contact dermatitis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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Appendix B: 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 (i.e. Elidel) should be reserved for second line therapy in patients who fail standard interventions, including low to mid potency topical corticosteroids.
- The long-term safety of Elidel has not been established beyond one year of non-continuous use.
- Patients with Netherton`s syndrome should not use Elidel due to potential increase in absorption.
- Pimecrolimus cream should *not* be used in immunocompromised adults or children.
- Based on the available data, the routine use of Elidel for vitiligo is supported at this time.
- Based on the available data, the routine use of Elidel for the treatment of allergic contact dermatitis is not supported at this time.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
Very High Potency		
augmented betamethasone 0.05% (Diprolene®), gel		Should not be used for longer than 2 consecutive weeks

Drug	Dosing Regimen	Dose/Limit/Maximum Dose
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution	Apply topically to the affected area(s) BID	
diflorasone diacetate 0.05% (Apexicon®Psorcon ®) ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency		
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		
fluocinonide acetonide 0.05% cream, ointment, gel, solution		
triamcinolone acetonide 0.5% cream, ointment		
Desoximetasone 0.25% (Topicort®) cream, ointment		
Medium Potency		
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		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% cream, ointment		
Low Potency		
alclometasone 0.05% (Aclovate®) cream, ointment	Apply topically to the affected area(s) BID	Should not be used for longer than 2 consecutive weeks
desonide 0.05% (Desowen®) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar®) solution		
hydrocortisone 2.5% (Ala-Cort®) cream		

V. Dosage and Administration

Elidel		
Indication	**Dosing Regimen**	**Maximum Dose**
Moderate atopic dermatitis	Apply a thin layer topically to affected skin BID. Reconfirm	2 applications/day

	diagnosis if no improvement after 6 weeks.	
Vitiligo	Apply a thin layer topically to affected skin BID	2 applications/day

VI. Product Availability

Drug	Availability
Elidel	Cream: 1%

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	1.12.17	8.17

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.