Clinical Policy: Pimecrolimus (Elidel)

Reference Number: CP.PMN.98
Effective Date: 12.01.14
Last Review Date: 02.18
Line of Business: Commercial, Health Insurance Marketplace

Revision Log

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

Description

Pimecrolimus (Elidel®) is a calcineurin inhibitor immunosuppressant.

FDA Approved Indication(s)

Elidel is indicated as 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(s) of use: Elidel 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. Member must meet one of the following (a, b, or c):
   a. Children and adolescents: Previous use of 2 medium potency corticosteroids in the previous 6 months, unless contraindicated or clinically significant adverse effects are experienced;
   b. Adults: Previous use of 2 high or very high potency corticosteroids in the previous 6 months, unless contraindicated or clinically significant adverse effects are experienced;
   c. Use on the face or skinfolds;
4. Request does not exceed a 30 gm tube per month.

Approval duration:
Health Insurance Marketplace – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Atopic Dermatitis, Vitiligo (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. Request does not exceed a 30 gm tube per month.

Approval duration:
Health Insurance Marketplace – 12 months
Commercial – Length of Benefit

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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

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 and HIM.PHAR.21 for health insurance marketplace.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym 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 (i.e., Elidel) 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

VI. Product Availability

Cream: 1%

VII. References

1. Elidel Prescribing Information. Quebec, Canada: Valeant Pharmaceuticals International Inc; June 2017. Available at http://www.elidel-us.com. November 24, 2017.
2. 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
HIM.PA. 56: Changed guideline to new format. Streamlined approval criteria. Removed previous section C. (Member must be at an FDA approved age for use: Pimecrolimus 1% cream ≥ 2 years of age, Tacrolimus 0.03% ointment ≥ 2 years of age Tacrolimus 0.1% ointment ≥ 16 years of age).	08.16	08.16
CP.CPA.25: Converted to new template; minor changes to verbiage and grammar. References updated.	01.12.17	08.17
HIM.PA.56: Converted to new template and updated the name of the policy to reflect the only drug referenced in the policy.	04.17	08.17
1Q18 annual review: - Policies combined for HIM and Commercial lines of business. - Renaming to PMN due to multiple line of business usage - References reviewed and updated.	11.24.17	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.

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 Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.