

PHARMACY BENEFITS MANAGER P.221 Approval Criteria

Dermatologic Agents

I. Medications:

- a. Tacrolimus Ointment (Protopic®)
- b. Crisaborole (Eucrisa®)
- c. Pimecrolimus (Elidel®)

II. Medication Classes:

- a. Dermatological Calcineurin Inhibitors
- b. Dermatological Phosphodiesterase-4 Enzyme Inhibitor

III. FDA Approved Uses:

- a. *Tacrolimus:* For the treatment of moderate to severe atopic dermatitis in immunocompetent patients not responsive to first line topical conventional therapy or when first line topical conventional therapies are not appropriate.
- b. Eucrisa: Atopic Dermatitis
- c. *Pimecrolimus:* Second-line therapy for short-term and non-continuous long-term treatment of mild to moderate atopic dermatitis in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

IV. Application of Criteria:

a. The following criteria apply to Illinois Medicaid

V. Criteria for Use:

- a. FDA approved indication as detailed above
- b. Documentation of trial and failure of one (1) topical corticosteroid OR
- c. Clinical reasoning as to why treatment with topical corticosteroids is not appropriate including but not limited to:
 - 1. Previous inadequate response
 - 2. Skin atrophy
 - 3. Use on an area of the body at high risk for skin atrophy such as the face or skin folds
- d. <u>Eucrisa only:</u> Trial and failure of one topical corticosteroid or one topical calcineurin

VI. Required Medical Information:

- a. Documentation of moderate to severe dermatitis
- b. Documentation of trial and failure of one first line topical corticosteroid for at least one month or documented contraindication to first line topical corticosteroids, or trial and failure of topical calcineurin (Eucrisa only)
- c. Chart notes showing compliance to previous therapy and office visits



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VII. Contraindications:

- a. Hypersensitivity to the medication or any components of its formulation
- b. Immunocompromised patient

VIII. Not Approved If:

- a. Patient does not meet criteria
- b. Failure to provide the required medical information needed to meet criteria.

IX. Length of Authorization:

- a. Initial: 3 months
- b. Continuation: up to 1 year

X. Criteria for continuation of therapy:

- a. Initial therapy was tolerated
- b. Follow up office visit notes after initiation of therapy with verified compliance and improvement on drug, and prescriber deeming it necessary to continue treatment

XI. Criteria for discontinuation of therapy:

- a. Patient is noncompliant with medical or pharmacologic therapy
- b. No demonstrable improvement in clinical condition has occurred after initiation of drug therapy after 6 weeks of treatment
- c. Patient experiences adverse drug reaction associated with therapy.

XII. References:

- a. Protopic [package insert]. Deerfield, IL: Astellas Pharmaceuticals America; November 2011.
- b. Ashcroft DM, Dimmock P, Garside R, et al. Efficacy and tolerability of topical pimecrolimus and tacrolimus in the treatment of atopic dermatitis: meta-analysis of randomised controlled trials. BMJ 2005; 330:516.

Approved by:		Date:	
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