

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Elidel (pimecrolimus) and Protopic (tacrolimus)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Elidel (pimecrolimus)	May be subject to quantity limit
Protopic (tacrolimus)	

### APPROVAL CRITERIA

Requests for Elidel or Protopic 0.03% may be approved for the following:

- I. Individual is equal to or greater than 2 years of age **AND**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one topical prescription corticosteroid; **OR**
- III. Use of a topical prescription corticosteroid agent may not be appropriate due to concomitant clinical situations such as but not limited to the following (AAD 2014):
  - A. Individual has atopic dermatitis recalcitrant to topical corticosteroids; **OR**
  - B. Individual has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds); **OR**
  - C. Individual has steroid-induced atrophy; **OR**
  - D. Individual has history of long-term or uninterrupted topical steroid use.

Requests for Protopic 0.1% may be approved for the following:

- I. Individual is equal to or greater than ( $\geq$ ) 16 years of age; **AND**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one topical prescription corticosteroid; **OR**
- III. Use of topical prescription corticosteroid agent may not be appropriate due to concomitant clinical situations such as but not limited to the following (AAD 2014):
  - A. Individual has atopic dermatitis recalcitrant to topical corticosteroids; **OR**
  - B. Individual has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds); **OR**
  - C. Individual has steroid-induced atrophy; **OR**
  - D. Individual has history of long-term or uninterrupted topical steroid use.

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**Note:**

Elidel (pimecrolimus) and Protopic (tacrolimus) both have a black box warning for malignancy (for example, skin and lymphoma). Continuous long-term use of any age and application to areas not involved with atopic dermatitis should be avoided. Use of Elidel and Protopic 0.03% should be limited to individuals aged 2 years or older. Protopic 0.1% is not indicated for use in children less than 16 years of age.

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 9, 2015.

DRUGDEX® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Eichenfield LL. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies.. Journal of the American Academy of Dermatology. 2014-01;71:116.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.