

# 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 (pimecrolimus) or Protopic (tacrolimus) 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 2014/2020, Eleftheriadou, 2022):
  - A. Individual has atopic dermatitis, psoriasis, or vitiligo recalcitrant to topical corticosteroids; **OR**
  - B. Individual has atopic dermatitis, psoriasis, or vitiligo 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 (tacrolimus) 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 2014/2020, Eleftheriadou, 2022):
  - a. Individual has atopic dermatitis, psoriasis, or vitiligo recalcitrant to topical corticosteroids; **OR**
  - b. Individual has atopic dermatitis, psoriasis, or vitiligo 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 **brand** Elidel or Protopic must also meet the following criteria, in addition to the above Prior Authorization criteria:

- I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic agent;

**AND**

- A. Generic had inadequate response; **OR**
- B. Generic caused adverse outcome; **OR**
- C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Note: Elidel (pimecrolimus) and Protopic (tacrolimus) both have a black box warning of 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 (pimecrolimus) and Protopic (tacrolimus) 0.03% should be limited to individuals aged 2 years or older. Protopic (tacrolimus) 0.1% is not indicated for use in children less than 16 years of age.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 22, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Eichenfield L. 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.
6. Eleftheriadou, V et al. "British Association of Dermatologists guidelines for the management of people with vitiligo 2021." *The British journal of dermatology* vol. 186,1 (2022): 18-29. doi:10.1111/bjd.20596
7. Elidel (pimecrolimus cream). 2001. Revised 12/2017. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available at [file:///C:/Users/AF38863/Downloads/20191218\\_e4027e5a-0f9b-4070-b196-f60172f45c4c.pdf](file:///C:/Users/AF38863/Downloads/20191218_e4027e5a-0f9b-4070-b196-f60172f45c4c.pdf). Accessed June 22, 2022
8. Menter A, Gelfan JM, Connor C, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J AM Acad Dermatol*, 2020; 82(6): 1445-86.
9. Taieb, A et al. "Guidelines for the management of vitiligo: the European Dermatology Forum consensus." *The British journal of dermatology* vol. 168,1 (2013): 5-19. doi:10.1111/j.1365-2133.2012.11197.x

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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