

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2016 P 1028-4
Program	Prior Authorization/Notification
Medication	Elidel® (pimecrolimus) and Protopic® (tacrolimus)
P&T Approval Date	9/13/2005, 1/9/2007, 1/22/2008, 4/7/2009, 10/2009, 9/2010, 11/2011, 11/2012, 11/2013, 4/2016, 9/2016
Effective Date	12/1/2016; Oxford only: 12/1/2016

**1. Background:**

Elidel (pimecrolimus) 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. Protopic (tacrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable.

Both Elidel and Protopic have demonstrated efficacy in the treatment of plaque psoriasis, and the American Academy of Dermatology recommend Elidel and Protopic for specific cases of facial and intertriginous psoriasis or situations where a topical corticosteroid may be associated with skin atrophy. If a patient is greater or equal to 2 years of age (greater or equal to 16 years of age for Protopic .01%) and has a prescription for a topical corticosteroid in claim's history in the previous 365 days, the prescription for Elidel or Protopic will automatically process.

**2. Coverage Criteria:**

<p><b>A.</b> Elidel will be approved based on <b><u>all</u></b> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Patient is 2 years of age or greater</li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>2. <b><u>One</u></b> of the following:             <ol style="list-style-type: none"> <li>a. mild to moderate atopic dermatitis</li> <li>b. eczema</li> <li>c. psoriasis</li> <li>d. vitiligo</li> </ol> </li> </ol> <p style="text-align: center;"><b>-AND-</b></p>
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3. **One** of the following:
  - a. history of failure, contraindication or intolerance to a topical corticosteroid
  - b. drug is being prescribed for the facial or groin area

**Authorization will be issued for 6 months**

**B.** Protopic 0.03% will be approved based on all of the following criteria:

1. Patient is 2 years of age or greater

**-AND-**

2. **One** of the following:
  - a. moderate to severe atopic dermatitis
  - b. eczema
  - c. psoriasis
  - d. vitiligo

**-AND-**

3. **One** of the following:
  - a. history of failure, contraindication or intolerance to a topical corticosteroid
  - b. drug is being prescribed for the facial or groin area

**Authorization will be issued for 6 months**

**C.** Protopic 0.1% will be approved based on all of the following criteria:

1. Patient is 16 years of age or greater

**-AND-**

2. **One** of the following:
  - a. moderate to severe atopic dermatitis
  - b. eczema
  - c. psoriasis
  - d. vitiligo

**-AND-**

3. **One** of the following:

- a. history of failure, contraindication or intolerance to a topical corticosteroid
- b. drug is being prescribed for the facial or groin area

**Authorization will be issued for 6 months**

**3. Additional Clinical Programs:**

- Supply limits may be in place.

**4. References:**

1. Elidel Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. August 2014.
2. Protopic Prescribing Information. Astellas Pharma US, Inc. Northbrook, IL May 2012.
3. American Academy of Dermatology. Guidelines of the Care for the Management of Psoriasis and Psoriatic Arthritis, Section 3. Guidelines of the Care for the Management of and Treatment of Psoriasis with Topical Therapies. J Am Acad Dermatol 2009; 60(4):643-59.
4. Gawkrödger DJ, Ormerod AD, Shaw L, Mauri-Sole I, Whitton ME, Watts MJ, Anstey AV, Ingham J, Young K; Therapy Guidelines and Audit Subcommittee, British Association of Dermatologists; Clinical Standards Department, Royal College of Physicians of London; Cochrane Skin Group; Vitiligo Society. Guideline for the diagnosis and management of vitiligo. Br J Dermatol. 2008 Nov;159(5):1051-76.

Program	Prior Authorization/Notification – Elidel and Protopic
<b>Change Control</b>	
Date	Change
11/2013	Annual review. Update references.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
4/2016	Clarified language to include history of failure, contraindication or intolerance to topical steroids. Updated references.
9/2016	Separated criteria for Protopic 0.1% and 0.03%. Revised age requirement for Protopic 0.1% for use in age 16 and above.