

Clinical Pharmacy Program Guidelines for Elidel and Protopic

Program	Prior Authorization
Medication	Elidel® (pimecrolimus) and Protopic® (tacrolimus)
Markets in Scope	Arizona, Colorado, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2011
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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 0.03% & 0.1% strengths are indicated for adults, and only the 0.03% is indicated for children aged 2 to 15 years.

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.

2. Coverage Criteria:

A. Elidel or Protopic will be approved based on the following criteria:

1. **One** of the following:

- (a) The request is for Elidel or Protopic 0.03% and the patient is 2 years of age or older
- (b) The request is for Protopic 0.1% and the patient is 16 years of age or older

-AND-

2. **One** of the following:

(a) History of failure, contraindication, or intolerance to **one** topical corticosteroid in the past 90 days.

-OR-

(b) Drug is being prescribed for the facial or groin area

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Elidel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals Inc; December 2017.
2. Protopic [package insert]. Northbrook, IL: Astellas Pharma US, I
3. Menter A, Korman NJ, et al. “Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies.” J Am Acad Dermatol 2009;60:643-59.

Program	Prior Authorization– Elidel and Protopic
Change Control	
Date	Change
9/2009	Criteria were taken from a previously approved AmeriChoice policy. Members aged 2-11 will no longer need prior authorization. Policy was reformatted.
12/2010	Protopic changed to an automated step therapy. Protopic authorization no longer requires the use of Elidel in addition to two topical corticosteroids as pre-requisite therapy, now only requires two previous trials of topical corticosteroids.
12/2011	Annual Review. No clinical changes. Updated references.
12/2012	Annual Review. Updated references.
4/2016	Updated policy to new template. Updated language to include history of failure, contraindication or intolerance to topical steroids, was previously two topical

	<p>corticosteroids.</p> <p>Added new diagnosis requirement to the criteria sections, except the automated step therapy section</p>
8/2016	<p>Removed vitiligo as a coverable diagnosis.</p> <p>Added Protopic 0.1% age check to section C- Protopic.</p>
9/2016	<p>Updated background information to clarify the minimum age requirement for Protopic 0.1%.</p>
3/2017	<p>Changed authorization durations from 6 months to 12 months.</p> <p>Updated policy template.</p>
9/2017	<p>Updated clinical criteria to align with Employer and Individual's step therapy policy since notification policy will be archived.</p>
12/2017	<p>Added age requirement back into policy since age edit is still coded and to ensure safe/appropriate use of the medications</p>
8/2018	<p>Revised lookback for step therapy in background and lookback to match coding. Updated references.</p>
8/2019	<p>Annual Review. Updated references, adding citation for the American Academy of Dermatology recommendation. Corrected spelling and formatting.</p>
9/2020	<p>Annual review. Added Additional Clinical Rules section and updated references.</p>