UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Elidel and Protopic

Program	Prior Authorization
Medication	Elidel® (pimecrolimus) and Protopic® (tacrolimus)
Issue Date	6/2011
Pharmacy and Therapeutics Approval Date	12/2017
Effective Date	2/2018

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 intertiginous 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 0.1%) 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:

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

1. **<u>One</u>** 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. **<u>One</u>** of the following:

   (a) History of failure, contraindication, or intolerance to **<u>one</u>** topical corticosteroid

-OR-

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

Authorization will be issued for 12 months.

3. References:

1. Elidel Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. June 2017.
2. Protopic Prescribing Information. Astellas Pharma US, Inc. Deerfield, IL May 2012.

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 corticosteroids. Added new diagnosis requirement to the criteria sections, except the automated step therapy section
8/2016	Removed vitiligo as a coverable diagnosis. Added Protopic 0.1% age check to section C- Protopic.
9/2016	Updated background information to clarify the minimum age requirement for Protopic 0.1%.

3/2017	Changed authorization durations from 6 months to 12 months. Updated policy template.
9/2017	Updated clinical criteria to align with Employer and Individual's step therapy policy since notification policy will be archived.
12/2017	Added age requirement back into policy since age edit is still coded and to ensure safe/appropriate use of the medications