I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy and Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs Pimecrolimus (Elidel) & Tacrolimus (Protopic) are subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Pimecrolimus (Elidel) and Tacrolimus (Protopic).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. **PROCEDURE**

- Pimecrolimus (Elidel) is indicated as second-line treatment for short-term and non-continuous chronic treatment of mild-to-moderate atopic dermatitis in non-immunocompromised adults and children two (2) years of age and older, who have failed to respond to other topical prescription treatments or when those treatments are not advisable.
- Tacrolimus (Protopic) 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 or when those treatments are not advisable.
- Both products have black box warnings which caution against the following:
  - Long-term safety of topical calcineurin inhibitors has not been established.
  - Rare cases of malignancy (e.g., skin and lymphoma) have been reported with topical calcineurin inhibitor use.
  - Continuous long-term use in any age group should be avoided and application limited to areas of involvement with atopic dermatitis.
  - Not indicated for use in children less than two (2) years of age.

**Criteria:**

- Tacrolimus (Protopic) and Pimecrolimus (Elidel) will be covered for members who meet the following criteria:
  - Have a diagnosis of atopic dermatitis (eczema);
  - Over the age of two (2);
  - Do not have a weakened or compromised immune system;
  - Failed a moderate-to-high potency topical corticosteroid; or
  - Have a contraindication/intolerance to topical corticosteroid therapy such as dermatitis on the face

- If the above criteria are met, initial approval will be for three (3) months.

**Reauthorization Criteria:**

- Extending the authorization for an additional three (3) months will be considered upon review of chart documentation from the prescriber indicating that the member’s signs and symptoms (e.g., rash, itch, and redness) have improved as a result of therapy.
- Authorization for therapy will be limited to six (6) months in a twelve (12) month period to ensure appropriate short-term use.

**Limitations:**

If a member does not meet the above approval criteria, the request will be sent to the UPMC Health Plan Medical Director for review.
VI. BIBLIOGRAPHY