PROPOSED PRIOR AUTHORIZATION CRITERIA

TOPICAL IMMUNOMODULATORS

Background

At the March 22, 2007, P&T Meeting, this drug class was reviewed. Both available products were added to the Preferred Drug List. Based on the product labeling and the FDA Public Health Advisory, the P&T Committee has requested that the DUR Board consider implementing appropriate PA criteria for this drug class.

The Drug Class review and the FDA Public Health Advisory are provided for your review.

Proposed PA Criteria- Elidel® and Protopic®

1) Patient must have a therapeutic failure with the use of a topical steroid

2) Diagnosis to approve – Atopic Dermatitis
   - Elidel® - mild to moderate for ages ≥ 2 years
   - Protopic® 0.03% - moderate to severe for ages ≥ 2 years
   - Protopic® 0.1% - moderate to severe for all ages ≥ 18 years

3) Not for chronic use

4) Elidel® is not recommended for use on patients with Netherton's syndrome due to the potential for systemic absorption.

5) Not recommended for use in immunocompromised patients.

6) Quantity Limits
   - Elidel® 1% Cream: 30g per 30 rolling days with a 25% tolerance for refills
   - Protopic® 0.03% and 0.1% Ointment: 30g per 30 rolling days with a 25% tolerance for refills