Drug Therapy Guidelines

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Topical Immunomodulators- Elidel® (pimecrolimus cream), Eucrisa® (crisaborole ointment), pimecrolimus cream</th>
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<td>Pharmacy- Formulary 1</td>
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<td>Next Review: 9/20</td>
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I. Medication Description

It has been demonstrated that pimecrolimus binds with high affinity to macrophilin-12 (FKBP-12) and inhibits the calcium-dependent phosphatase, calcineurin. As a consequence, it inhibits T-cell activation by blocking the transcription of early cytokines. In addition, pimecrolimus prevents the release of inflammatory cytokines and mediators from mast cells in vitro after stimulation by antigen/IgE.

Crisaborole has been found to increase intracellular concentrations of cyclic adenosine monophosphate (cAMP) by inhibiting phosphodiesterase-4 (PDE-4). Phosphodiesterase-4 is an enzyme that regulates production of inflammatory cytokines through the degradation of cAMP. In patients with atopic dermatitis, PDE-4 activity is enhanced in circulating inflammatory cells resulting in increased cytokine production. By inhibiting the ability of PDE-4 to degrade cAMP, crisaborole suppresses the release of pro-inflammatory cytokines.

II. Position Statement

Coverage is provided immediately if a paid claim for a topical steroid is found in the pharmacy history within the last 365 days.

Coverage is determined through a prior authorization process with supporting clinical documentation for all other requests.

III. Policy

Coverage will be provided as follows:

- When requesting coverage of a brand medication for which an A/B rated generic is available, coverage will be provided when there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
- One of the following is confirmed:
  - Member has a dermatologic condition on or around the eyes/eyelids, axilla, or genitalia OR
  - Member has steroid-induced rosacea OR
  - Member has experienced intolerance or therapeutic failure with at least one plan-preferred medication (a prescription strength topical corticosteroid) at any time in the past for their diagnosis OR at least ONE of the following criteria have been met:
    - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
- The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).
- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

Coverage granted for quantities sufficient to fulfill FDA-approved dosing.

V. Coverage Duration

Coverage will be granted indefinitely through the life of this policy once the initial criteria are met.

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

- Elidel: 1% topical cream
- Eucrisa: 2% topical ointment
- Pimecrolimus: 1% topical cream

VIII. Summary of Policy Changes

- 3/15/13: new policy
- 3/15/14: no policy changes
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
• 9/15/16: no policy changes
• 4/3/17: Eucrisa added to policy
• 5/1/17: step therapy criteria added
• 10/16/17: no policy changes
• 11/1/18: no policy changes
• 11/13/18: Protopic/tacrolimus ointment removed from policy
• 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.