Topical Calcineurin Inhibitors - Pimecrolimus (Elidel®), Tacrolimus (Protopic®)
[Developed, October 2006; Revised, December 2006; May 2010; February 2012; December 2013]
MEDICAID DRUG USE REVIEW CRITERIA FOR OUTPATIENT USE

Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with [*].

1.* Dosage

Topical calcineurin inhibitors are FDA-approved as second-line agents for atopic dermatitis management in non-immunocompromised adults and children greater than 2 years of age who have not responded to other available therapies for atopic dermatitis. Pimecrolimus (Elidel®) is indicated for short-term, intermittent treatment of mild-to-moderate atopic dermatitis, while tacrolimus (Protopic®) is indicated for short-term, intermittent therapy of moderate-to-severe atopic dermatitis.

Adults
Dosage recommendations for available calcineurin inhibitors are summarized in Table 1.

Table 1. Recommended Adult Dosages For Topical Calcineurin Inhibitors

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosage Strength</th>
<th>Recommended Dose/Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>pimecrolimus (Elidel®) cream</td>
<td>1% - 30 g, 60g, 100 g tube</td>
<td>apply thin layer of cream to affected area twice daily until symptoms resolve; use should be confined only to areas affected by atopic dermatitis; should not be used with occlusive dressings</td>
</tr>
<tr>
<td>tacrolimus (Protopic®) ointment</td>
<td>0.03% - 30 g, 60 g, 100 g tube 0.1% - 30 g, 60 g, 100 g tube</td>
<td>apply thin layer of 0.03% or 0.1% ointment to affected area twice daily, rubbing in completely, and continue until symptoms resolve; use should be confined only to areas affected by atopic dermatitis; should not be used with occlusive dressings</td>
</tr>
</tbody>
</table>

Patient profiles documenting prescriptions for greater than the equivalent of one 60 g tube of pimecrolimus cream or tacrolimus ointment per 30 day time period will be reviewed.

Pediatrics
A potential cancer risk (e.g., skin cancer, lymphoma) has been associated with use of pimecrolimus cream and tacrolimus ointment based on information from animal studies, a small number of case reports as well as the proposed mechanism of action of calcineurin inhibitors. While a causal relationship has not been established, topical calcineurin inhibitor use should be avoided in children younger than 2 years of age as the effect on the developing immune system is not known. Recommended pediatric dosages for topical calcineurin inhibitors are summarized in Table 2.
Table 2. Recommended Pediatric Dosages for Topical Calcineurin Inhibitors

<table>
<thead>
<tr>
<th>Drug Name/Strength</th>
<th>Recommended Dose/Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>pimecrolimus 1% cream</td>
<td><em>Children &gt; 2 years of age:</em> apply thin layer of cream to affected area twice daily until symptoms resolve; use should be confined only to areas affected by atopic dermatitis; should not be used with occlusive dressings</td>
</tr>
<tr>
<td>tacrolimus 0.03% ointment</td>
<td><em>Children 2-15 years of age:</em> use only 0.03% strength; apply thin layer of ointment to affected layer twice daily, rubbing in completely, and continue until symptoms resolve; use should be confined only to areas affected by atopic dermatitis; should not be used with occlusive dressings</td>
</tr>
<tr>
<td>tacrolimus 0.1% ointment</td>
<td><em>Children 15-17 years of age:</em> apply thin layer of 0.03% or 0.1% ointment to affected area twice daily, rubbing in completely, and continue until symptoms resolve; use should be confined only to areas affected by atopic dermatitis; should not be used with occlusive dressings</td>
</tr>
</tbody>
</table>

Patient profiles documenting prescriptions for greater than the equivalent of one 60 g tube of pimecrolimus cream or tacrolimus ointment per 30 day time period will be reviewed.

2. **Duration of Therapy**

Continuous, long-term use of topical calcineurin inhibitors should be avoided, and use should be confined only to areas affected by atopic dermatitis. *Patients whose symptoms do not resolve following six weeks of calcineurin inhibitor therapy should be re-evaluated by their health care provider to confirm the diagnosis of atopic dermatitis.*

Patients with a confirmed diagnosis of atopic dermatitis will require chronic, intermittent therapy for this condition. Patient profiles with either excessive prescriptions for calcineurin inhibitors during a 30 day time period (> 1 x 60 g tube) or without a definitive diagnosis of atopic dermatitis while prescribed a topical calcineurin inhibitor during a 90 day time period will be reviewed.

3.* **Duplicative Therapy**

Concurrent administration of two or more topical calcineurin inhibitors does not provide enhanced therapeutic benefit and may result in additive adverse effects. Concurrent administration of pimecrolimus cream and tacrolimus ointment is not recommended and will be reviewed.

REFERENCES


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