



# Medicaid Drug Use Criteria

## *Topical Calcineurin Inhibitors – Pimecrolimus (Elidel®), Tacrolimus (Protopic®)*

- Developed: October 2006
- Revised: November 2019; December 2017; August 2015; December 2013; February 2012; May 2010; December 2006.

Notes: Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [\*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

Prepared by:

- Drug Information Service, UT Health San Antonio
- The College of Pharmacy, The University of Texas at Austin

## 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.

## 1.1 Adults

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

**Table 1. Recommended Adult Dosages for Topical Calcineurin Inhibitors<sup>[1-6]</sup>**

Drug Name	Dosage Strength	Recommended Dose/Directions
pimecrolimus (Elidel®, generics) cream	1% - 30 g, 60g, 100 g tube	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
tacrolimus (Protopic®, generics) ointment	0.03% - 30 g, 60 g, 100 g tube 0.1% - 30 g, 60 g, 100 g tube	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

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.

## 1.2 Pediatrics <sup>[1-25]</sup>

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. Additionally, only the 0.03% tacrolimus ointment should be prescribed for pediatric patients 2 to 15 years of age. Recommended pediatric dosages for topical calcineurin inhibitors are summarized in Table 2.

**Table 2. Recommended Pediatric Dosages for Topical Calcineurin Inhibitors<sup>[1-6]</sup>**

<b>Drug Name/Strength</b>	<b>Recommended Dose/Directions</b>
pimecrolimus 1% cream	<i>Children greater than 2 years of age:</i> 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
tacrolimus 0.03% ointment	<i>Children 2-15 years of age:</i> 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
0.03% or 0.1% ointment	<i>Children 15-17 years of age:</i> 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

## **2 Duration of Therapy<sup>[1-25]</sup>**

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 (greater than 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.

### 4 References

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