

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Topical Agents for Atopic Dermatitis Drug Quantity Management Policy – Per Days

- Elidel® (pimecrolimus 1% cream – Bausch/Valeant, generic)
- Eucrisa® (crisaborole 2% ointment – Pfizer)
- Protopic® (tacrolimus 0.03% and 0.1% ointment – LEO Pharma, generic)

REVIEW DATE: 10/12/2022

OVERVIEW

Eucrisa, pimecrolimus cream, and tacrolimus ointment are all indicated for **atopic dermatitis**.¹⁻³

- Eucrisa, a phosphodiesterase 4 inhibitor, is indicated for the topical treatment of **mild to moderate atopic dermatitis in patients ≥ 3 months of age**.
- Pimecrolimus cream is a calcineurin inhibitor indicated as second-line therapy for the short-term and non-continuous chronic treatment of **mild to moderate atopic dermatitis in non-immunocompromised patients ≥ 2 years of age** who have failed to respond adequately to other topical prescription treatments or when those treatments are not advisable.
- Tacrolimus ointment is also a calcineurin inhibitor and is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **moderate to severe atopic dermatitis in non-immunocompromised patients** who have failed to respond adequately to other topical prescription treatments or when those treatments are not advisable.
 - **Both tacrolimus 0.03% and 0.1% ointment** are indicated for use in **adults**; **tacrolimus 0.03% ointment** is also indicated for use in **patients 2 to 15 years of age**.

Dosing/Availability

Table 1. FDA-Approved Indications and Availability.¹⁻³

Brand (Generic)	Dosing	Availability
Eucrisa® (crisaborole ointment)	Apply as a thin layer BID to affected areas.	2% ointment; available in 60 g and 100 g tubes
tacrolimus ointment (Protopic®, generic)	Apply as a thin layer BID to affected areas. <ul style="list-style-type: none"> • Stop using when signs and symptoms of atopic dermatitis resolve. • If signs and symptoms do not improve within 6 weeks, patients should be re-examined by their healthcare provider to confirm the diagnosis of atopic dermatitis. • Continuous long-term use of topical calcineurin inhibitors should be avoided, and application should be limited to areas of involvement with atopic dermatitis. 	0.03% ointment and 0.1% ointment; both available in 30 g, 60 g, and 100 g tubes
pimecrolimus cream, (Elidel®, generic)	Apply as a thin layer BID to affected areas. <ul style="list-style-type: none"> • Stop using when signs and symptoms of atopic dermatitis resolve. • If signs and symptoms do not improve within 6 weeks, patients should be re-examined by their healthcare provider to confirm the diagnosis of atopic dermatitis. Continuous long-term use of topical calcineurin inhibitors should be avoided, and application should be limited to areas of involvement with atopic dermatitis.	1% cream; available in 30 g, 60 g, and 100 g tubes

BID – Twice daily.

Application Information

The clinical presentation of atopic dermatitis differs depending on age.⁴ In infants, the face, scalp, trunk, and extremities are most often impacted. Older children generally present with patches on flexural surfaces, and adults present with patches on extremities. The SCORing Atopic Dermatitis (SCORAD) index is the most widely used validated clinical tool to classify atopic dermatitis severity based on affected body surface area (BSA) and intensity of the lesions.⁵⁻⁷ The head and neck are considered 9% of BSA, each upper limb is 9% of BSA (18% total), each lower limb is 18% BSA (36% total), anterior tuck is 18% of BSA, back is 18% of BSA, and genitals are 1% of BSA. In clinical trials of pimecrolimus and tacrolimus, 75% to 80% of patients had atopic dermatitis affecting the face and/or neck region.^{1,2}

For topical product application, a standard measure, the finger-tip unit (FTU), is often used.⁵ One FTU is the amount of product that is squeezed out of a standard tube along an adult’s fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult’s total body surface area (BSA). For children, an FTU is still the amount of product that will fit on an adult’s index fingertip. The amount of BSA that the application will cover depends on the size of the child.

Based on the FTU method, 120 grams provides enough product to cover approximately 8% of the patient’s BSA when applying two times daily for 30 days.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse use of the topical agents for atopic dermatitis. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Package size	Retail Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 days
Eucrisa® (crisaborole 2% ointment)	60 gram tube	120 grams*	360 grams ^a
	100 gram tube		
tacrolimus 0.03% and 0.1% ointment (Protopic®, generic)	30 gram tube	120 grams*	360 grams ^a
	60 gram tube		
	100 gram tube		
pimecrolimus 1% cream (Elidel®, generic)	30 gram tube	120 grams*	360 grams ^a
	60 gram tube		
	100 gram tube		

* This is a quantity sufficient to apply to approximately 8% of the body surface area when applying twice daily for 30 days; ^a This is a quantity sufficient to apply to approximately 8% of the body surface area when applying twice daily for 90 days.

CRITERIA

Eucrisa 2% ointment

1. If the patient has mild to moderate atopic dermatitis and needs to treat greater than 8% of their body surface area or administer more frequently than twice daily, approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery.

Tacrolimus 0.03% and 0.1% ointment (Protopic, generic)

1. If the patient has moderate to severe atopic dermatitis and needs to treat greater than 8% of their body surface area or administer more frequently than twice daily, approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery.

Pimecrolimus 1% cream (Elidel, generic)

2. If the patient has mild to moderate atopic dermatitis and needs to treat greater than 8% of their body surface area or administer more frequently than twice daily, approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery.

EXCLUSIONS

1. No overrides are recommended for use in compounded formulations.

REFERENCES

1. Elidel® 1% cream [prescribing information]. Bridgewater, NJ: Bausch; September 2020.
2. Protopic® 0.03% and 0.1% ointment [prescribing information]. Madison, NJ: LEO Pharma; June 2022.
3. Eucrisa® 2% ointment [prescribing information]. New York, NY: Pfizer; March 2020.
4. Fazio SB, Yosipovitch G. Pruritus: Therapies for localized pruritus. Last updated July 2021. In T.W. Post, P. Rutgeerts, & S. Grover (Eds.), *UptoDate*. Available from: https://www.uptodate.com/contents/pruritus-therapies-for-localized-pruritus?search=lichen%20simplex%20chronicus§ionRank=1&usage_type=default&anchor=H45580783&source=mac hineLearning&selectedTitle=1~43&display_rank=1#H171003115. Accessed on September 28, 2022.
5. Eichenfeld LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. *J Am Acad Dermatol*. 2014;71:116-132.
6. Frazier W and Bhardwaj N. Atopic dermatitis: diagnosis and treatment. *Am Fam Phys*. 2020;101:590-598. Available at: <https://www.aafp.org/pubs/afp/issues/2020/0515/p590.html>. Accessed on September 28, 2022.
7. SCORing Atopic Dermatitis Calculator (SCORAD 0.9.0). Available at: <https://scorad.corti.li/>. Accessed on September 28, 2022.

