



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, generic)

REVIEW DATE: 10/23/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 2% ointment)	Apply as a thin layer BID to affected areas. Once clinical effect is achieved, consider reducing application to QD.	60 g and 100 g tubes
tacrolimus 0.03% and 0.1% 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. 	30 g, 60 g, and 100 g tubes
pimecrolimus 1% 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. 	30 g, 60 g, and 100 g tubes

BID – Twice daily; QD – Once 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 trunk 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.

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.

Topical Agents for Atopic Dermatitis Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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; June 2022.
3. Eucrisa® 2% ointment [prescribing information]. New York, NY: Pfizer; April 2023.
4. Fazio SB, Yosipovitch G. Pruritis: Therapies for localized pruritus. Last updated July 2024. 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=machineLearning&selectedTitle=1~43&display_rank=1#H171003115. Accessed on October 09, 2024.
5. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
6. Frazier W and Bhardwaj N. Atopic dermatitis: diagnosis and treatment. *Am Fam Phys*. 2020;101:590-598.
7. SCORing Atopic Dermatitis Calculator. Available at: <https://www.mdapp.co/scoring-atopic-dermatitis-scorad-calculator-396/>. Accessed on October 09, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/16/2023
Annual Revision	No criteria changes.	10/23/2024

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