



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

Table of Contents

National Formulary Medical Necessity 1
 Conditions Not Covered.....2
 Background.....2
 References3
 Revision History.....4

Product Identifier(s)

Effective 1/1/23 to 2/27/23: 109142
Effective 2/28/23: 55480

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. 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.

National Formulary Medical Necessity

Drugs Affected

- Elidel® (pimecrolimus 1% cream – generic)
- Eucrisa® (crisaborole 2% ointment)
- Protopic® (tacrolimus 0.03% and 0.1% ointment – generic)

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.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Eucrisa 2% ointment

1. If the individual 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 individual 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)

1. If the individual 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.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

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

Background

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 individuals ≥ 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 individuals ≥ 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 individuals** 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 **individuals 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, individuals 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, individuals 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 individuals 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 individual's BSA when applying two times daily for 30 days.

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. Pruritis: 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=machineLearning&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.

Revision History

| Type of Revision | Summary of Changes | Approval Date |
|------------------|--|---------------|
| Annual Revision | <p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p>Tacrolimus 0.03% and 0.1% ointment (Protopic, generic): Quantity limit changed to 120 grams per 30 days at retail and 360 grams per 90 days at home delivery (previously limits were 100 grams per 30 days at retail and 300 grams per 90 days at home delivery). Override criteria updated to approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery if the patient needs to treat greater than 8% of their body surface area or administer more frequently than twice daily. Previously, this override criteria approved up to 200 grams per 30 days at retail and 600 grams per 90 days at home delivery if the patient needed to treat greater than 9% of their body surface area or administer more frequently than twice daily.</p> <p>Pimecrolimus 1% cream (Elidel, generic): Quantity limit changed to 120 grams per 30 days at retail and 360 grams per 90 days at home delivery (previously limits were 100 grams per 30 days at retail and 300 grams per 90 days at home delivery). Override criteria updated to approve the requested quantity not to exceed 240 grams per 30 days at retail and 720 grams per 90 days at home delivery if the patient needs to treat greater than 8% of their body surface area or administer more frequently than twice daily. Previously, this override criteria approved up to 200 grams per 30 days at retail and 600 grams per 90 days at home delivery if the patient needed to treat greater than 9% of their body surface area or administer more frequently than twice daily.</p> | 10/12/2022 |

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.