

Cigna National Preferred Formulary Coverage Policy



Effective Date 1/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number NPF236

Drug Quantity Management Policy – Per Days Topical Products for Atopic Dermatitis Duration Limit

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Related Coverage Resources

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.

NPF Coverage Policy

Drugs Affected

- pimecrolimus cream 1% (Elidel, generics)
- tacrolimus ointment 0.03%, 0.1% (Protopic, generics)
- crisaborole ointment 2% (Eucrisa)

A quantity of 100 grams of pimecrolimus cream, tacrolimus ointment, and a quantity of 120 grams of crisaborole ointment will be covered without prior authorization. This is enough drug to cover approximately 9% of the body surface area when applying two times daily for one month.

For coverage of additional quantities (for example, coverage of a larger surface area, more frequent administration), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse.

Criteria

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

All approvals are provided for 12 months in duration.

1. For individuals needing to treat greater than 9% of body surface area or administering more frequently than two times a day, an override of up to 200 grams per month can be approved for tacrolimus ointment or pimecrolimus cream and a quantity of 240 grams per month can be approved for crisaborole ointment.

Conditions Not Covered

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

1. No overrides are recommended for use in compounded formulations.
2. No overrides are recommended for any other indications not listed in the prescribing information.

Background

Overview

Pimecrolimus cream and tacrolimus ointment are indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable. Crisaborole is indicated for topical treatment of mild to moderate atopic dermatitis.

In clinical trials of pimecrolimus and tacrolimus, 75-80% of individuals had atopic dermatitis affecting the face and/or neck region.^{1,2} The most common areas of the body affected by atopic dermatitis are the face, chest and back of scalp in infants and young children.⁴ In older children and adults, the front of elbows, behind the knees, face, palms of hands and soles of feet are most commonly affected.⁴ The head and neck region, upper or lower chest, each leg, or each arm comprise approximately 9% of body surface area (BSA).⁵ References related to the quantity of topical creams and ointments needed to treat the involved body surface area of various dermatoses estimate that between 85 - 135 grams of ointment or cream would be needed to cover a 9% BSA region when applying two times daily for one month⁵. Pimecrolimus cream, tacrolimus ointment and crisaborole ointment are to be applied to the affected area two times daily.

References

1. Elidel® 1% cream [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America, LLC, December 2017.
2. Protopic® 0.03% and 0.1% ointment [prescribing information]. Madison, NJ: LEO Pharma. Inc., February 2019.
3. Eucrisa™ 2% ointment [prescribing information]. NY, NY: Pfizer, Inc., April 2020.
4. Atopic Dermatitis Practice Parameters. Ann Allergy Asthma Immunol. 2004; 93:S1-21.
5. Nelson A, Miller A, Fleischer A, Balkrishnan R, Feldman S. How much of a topical agent should be prescribed for children of different sizes? J Derm Treat 2006; 17:224-228.
6. Long CC, Finlay AY. The finger-tip unit—a new practical measure. Clin Exp Dermatol 1991 Nov; 16(6):444-7.

Last Revision Details

Annual Revision	Reviewed by Clinical Specialists. No criteria changes.	09/01/2020
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