STEP THERAPY CRITERIA

BRAND NAME*
(generic)

EUCRISA
(crisaborole)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization ***Ref # 1567-E***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
Eucrisa is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

INITIAL STEP THERAPY*
**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then a quantity limit will apply. If the patient is requesting more than the quantity limit, the claim will reject with a message indicating that a PA is required.

INITIAL LIMIT CRITERIA

Drug	1 Month Limit*	3 Month Limit*
Eucrisa (crisaborole)	60 grams (1 tube) per 25 days	180 grams (3 tubes) per 75 days

** The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

TABLE 1: EXAMPLES OF TOPICAL CORTICOSTEROIDS FOR TREATMENT OF ATOPIC DERMATITIS [3,7,10]	
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
	betamethasone valerate cream/lotion 0.1%/foam 0.12%
	clocortolone pivalate cream 0.1%
	desonide lotion, ointment 0.05%
	desoximetasone cream 0.05%
	fluocinolone acetonide cream/ointment/kit 0.025%
	flurandrenolide cream/ointment/lotion 0.05%
	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
	hydrocortisone probutate cream 0.1%
	hydrocortisone valerate cream/ointment 0.2%

	mometasone furoate cream/lotion/solution 0.1%
	prednicarbate cream/ointment 0.1%
	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
	triamcinolone acetonide cream/ointment/lotion 0.025%
	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
	betamethasone dipropionate cream/ointment 0.05%
	betamethasone dipropionate augmented cream/lotion 0.05%
	betamethasone valerate ointment 0.1%
	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%
	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
	halcinonide cream/ointment 0.1%
	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%
	mometasone furoate ointment 0.1%
	triamcinolone acetonide aerosol solution 0.147 mg/g
	triamcinolone acetonide cream/ointment 0.5%
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
	diflorasone diacetate ointment 0.05%
	flurandrenolide tape 4mcg/cm2
	halobetasol propionate cream/ointment/lotion/kit 0.05%
	fluocinonide cream 0.1%

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for a patient 2 years of age or older for mild to moderate atopic dermatitis

AND

  - The requested drug is being prescribed for use on sensitive skin areas (e.g., face, body skin folds, genital area, armpit, or around the eyes)
    AND
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor

OR

  - The requested drug is being prescribed for use on non-sensitive (or remaining) skin areas
    AND
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid

AND

- If additional quantities are being requested, then 5 percent or greater body surface area is affected

OR

- The requested drug is being prescribed for continuation of therapy, and the patient achieved or maintained positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation of papules), lichenification (epidermal thickening), OR pruritus (itching)]

AND

- If additional quantities are being requested, then 5 percent or greater body surface area is affected

RATIONALE

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria or is requesting more than the initial quantity limit, then prior authorization is required.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Eucrisa (crisaborole) is a topical phosphodiesterase-4 (PDE-4) inhibitor that is indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

Topical corticosteroids are first-line and topical calcineurin inhibitors are second-line treatment for atopic dermatitis.[4] The current study data compares crisaborole to a placebo vehicle making it difficult to compare efficacy to either class of agents currently recommended in the American Academy of Dermatology guidelines. Two phase 3 studies were completed to compare crisaborole to placebo. Two identically designed multicenter, randomized, double-blind, vehicle-controlled phase III clinical studies treating 1522 patients assessed the efficacy and safety of crisaborole in patients with mild to moderate Atopic Dermatitis. The patients were required to be 2 years or older with 5% or more treatable body surface area involvement and a baseline Investigator's Static Global Assessment (ISGA) score of mild (2) or moderate (3). The primary endpoint of each study was an improvement in Investigator's Static Global Assessment (ISGA) score to clear (0) or almost clear (1) with at least a 2 grade improvement from baseline after 29 days. Both studies showed a statistically significant difference in endpoints in comparison of crisaborole to placebo vehicle. In the first study, Trial 1 (AD-301), 32.8% of patients reached goal in the treatment group versus 25.4% in the control group. In the second study, Trial 2 (AD-302), 31.4% of treated patients and only 18.0% of control patient reached the endpoint goal. Comparison of crisaborole-treated with vehicle-treated patients at day 29 revealed a statistically significant improvement of the crisaborole-treated patients in signs and symptoms of atopic dermatitis: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation for papules), lichenification (epidermal thickening), or pruritus (itching). [5, 8]

The data show efficacy for crisaborole but did not compare it directly to topical corticosteroids or topical calcineurin inhibitors. Therefore, coverage for crisaborole will be considered if the patient has had an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid before the use of crisaborole.

TABLE 1: EXAMPLES OF TOPICAL CORTICOSTEROIDS FOR TREATMENT OF ATOPIC DERMATITIS [3,7,10]	
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
	betamethasone valerate cream/lotion 0.1%/foam 0.12%
	clocortolone pivalate cream 0.1%
	desonide lotion, ointment 0.05%
	desoximetasone cream 0.05%
	fluocinolone acetonide cream/ointment/kit 0.025%
	flurandrenolide cream/ointment/lotion 0.05%
	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
	hydrocortisone probutate cream 0.1%
	hydrocortisone valerate cream/ointment 0.2%
	mometasone furoate cream/lotion/solution 0.1%
	prednicarbate cream/ointment 0.1%
	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
	triamcinolone acetonide cream/ointment/lotion 0.025%
	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
	betamethasone dipropionate cream/ointment 0.05%
	betamethasone dipropionate augmented cream/lotion 0.05%
	betamethasone valerate ointment 0.1%
	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%
	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
	halcinonide cream/ointment 0.1%
	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%

	mometasone furoate ointment 0.1%
	triamcinolone acetonide aerosol solution 0.147 mg/g
	triamcinolone acetonide cream/ointment 0.5%
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
	diflorasone diacetate ointment 0.05%
	flurandrenolide tape 4mcg/cm2
	halobetasol propionate cream/ointment/lotion/kit 0.05%
	fluocinonide cream 0.1%

However, there are cases when topical corticosteroids are a cause for concern. These cases are instances of ongoing use and adverse events such as atrophy. Because topical calcineurin inhibitors and crisaborole do not lead to skin atrophy, they are particularly useful for sensitive areas on the face, body skin folds, genital area, armpit, or around the eyes.[4,5] In these cases coverage for crisaborole will be considered if the patient has had an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor

In order to assess whether Eucrisa is effective for the patient, initial approval will be for 3 months. For continuation of therapy, if the patient is showing a positive clinical response [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation of papules), lichenification (epidermal thickening), OR pruritus (itching)] then the request will be approved for 12 months.

Approved criteria will cover up to 60 gm per 30 days of the requested drug. This will allow twice daily application to approximately 4% body surface area (equivalent to approximately 4 palms) for each application.[9] If 5% or greater of the body surface area is affected, approved criteria will cover up to 120 gm per 30 days.

REFERENCES

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4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol* 2014;71:116-32.
5. Paller AS, Tom WL, et. al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *J Am Acad Dermatol.* 2016 Jul 11; 75 (3) 494-503.e4.
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for continuation of therapy? [If no, then skip to question 3.]	Yes	No
2	Has the patient achieved or maintained positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), exudation (oozing and crusting), excoriation (evidence of scratching), induration (hardening)/papulation (formation of papules), lichenification (epidermal thickening), OR pruritus (itching)]? [If yes, then skip to question 7.]	Yes	No
3	Is the requested drug being prescribed for a patient 2 years of age or older for mild to moderate atopic dermatitis?	Yes	No
4	Is the requested drug being prescribed for use on sensitive skin areas (e.g., face, body skin folds, genital area, armpit, or around the eyes)? [If no, then skip to question 6.]	Yes	No
5	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor? [If yes, then skip to question 10.]	Yes	No
6	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor AND a medium or higher potency corticosteroid? [If yes, then skip to question 10.]	Yes	No
7	Coverage is provided for up to 60 gm per 30 days. If higher quantities are needed, additional questions are required. Is MORE than this quantity needed to treat the affected area? [If no, then no further questions.]	Yes	No
8	Does the patient need an additional quantity to cover a 5 percent or greater body surface area? [RPh Note: If no, then deny and enter a partial approval for 60 gm per 25 days.]	Yes	No
9	Does the patient require MORE than 120 gm per 30 days? [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for 120 gm per 25 days.]	Yes	No
10	Coverage is provided for up to 60 gm per 30 days. If higher quantities are needed, additional questions are required. Is MORE than this quantity needed to treat the affected area? [If no, then no further questions.]	Yes	No
11	Does the patient need an additional quantity to cover a 5 percent or greater body surface area? [RPh Note: If no, then deny and enter a partial approval for 60 gm per 25 days.]	Yes	No
12	Does the patient require MORE than 120 gm per 30 days? [RPh Note: If yes, then deny and enter a partial approval for 120 gm per 25 days.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 3	
2.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it and have shown improvement. Your request has been denied based on the information we have. [Short Description: Continuation of therapy, no response to treatment]
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are have these conditions: - You are 2 years of age or older - You have mild to moderate atopic dermatitis Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
4.	Go to 5	Go to 6	
5.	Go to 10	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have these conditions: - You are using this drug on sensitive skin areas (e.g., face, body skin folds, genital area, armpits or around the eyes) - You tried a topical calcineurin inhibitor and it did not work for you or you cannot use it Your request has been denied based on the information we have. [Short Description: No trial of calcineurin inhibitors]
6.	Go to 10	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have these conditions: - You tried a topical calcineurin inhibitor and it did not work for you or you cannot use it - You tried a medium or higher potency topical corticosteroid and it did not work for you or you cannot use it Your request has been denied based on the information we have. [Short Description: No trial of topical corticosteroids, calcineurin inhibitors]
7.	Go to 8	Approve, 12 months, 60 gm/month	
8.	Go to 9	Deny	You do not meet the requirements of your plan. Your plan covers additional quantities of this drug when you need more of this drug to cover a 5 percent or greater body surface area. Current plan approved criteria cover up to 60 grams per month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]
9.	Deny	Approve, 12 months, 120 gm/month	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 120 grams per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

10.	Go to 11	Approve, 3 months, 60 gm/month	
11.	Go to 12	Deny	You do not meet the requirements of yoru plan. Your plan covers additional quantities of this drug when you need more of this drug to cover a 5 percent or greater body surface area. Current plan approved criteria cover up to 60 grams per month of the requested drug and strength. You have been approved for the quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]
12.	Deny	Approve, 3 months, 120 gm/month	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 120 grams per month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 3 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]