

Topical Immunomodulators
Eucrisa (crisaborole)
Opzelura (ruxolitinib)
Effective 9/01/2022

Plan	<input checked="" type="checkbox"/> MassHealth (UPPL) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Eucrisa[®] (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

Opzelura[®] (ruxolitinib) is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

No PA	Drugs that require PA
Elidel [®] (pimecrolimus) §	Eucrisa [®] (crisaborole) ^{PD}
Protopic [®] # (tacrolimus topical)	Opzelura [®] (ruxolitinib)

^{PD} Preferred Drug: A trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Immune Suppressants – Topical agents, a trial with a preferred agent is not required prior to approval of a non-preferred agent.

§ Brand Preferred over generic equivalents: A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule or liquid) does not have an FDA "A"-rated generic equivalent.



Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets **ALL** following criteria and documentation has been submitted:

Eucrisa[®] (crisaborole)

Prescriber provides documentation of ALL of the following:

1. Diagnosis of atopic dermatitis (eczema)
2. Member is ≥ 3 months of age
3. The member meets **ONE** of the following:
 - a. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** topical corticosteroid **OR** topical calcineurin inhibitor (e.g. pimecrolimus or tacrolimus)
 - b. Contraindication to **BOTH** topical corticosteroids and topical calcineurin inhibitors
4. **ONE** of the following:
 - a. Request is for 60 gram/month. If the request does not document quantity, may be approved for the 60 gram/month if member meets criteria.
 - b. Medical necessity for exceeding the quantity limits (i.e. large surface area of lesion)

Opzelura[®] (ruxolitinib)

Prescriber provides documentation of ALL of the following:

1. Diagnosis of atopic dermatitis
2. Member is ≥ 12 years of age
3. The member meets **ONE** of the following:
 - a. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** topical corticosteroid **OR** topical calcineurin inhibitor (e.g. pimecrolimus or tacrolimus)
 - b. Contraindication to **BOTH** topical corticosteroids and topical calcineurin inhibitors
4. Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to Eucrisa[®] (crisaborole)
5. **ONE** of the following:
 - a. Request is for 60 grams/month. If the request does not document quantity, may be approved for 60 grams/month if member meets criteria.
 - b. Medical necessity for exceeding the quantity limits (i.e. large surface area of lesion)

Continuation of Therapy

Reauthorizations by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for up to 3 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

Eucrisa	60 grams per 30 days
Opzelura	60 grams per 30 days

Brand preferred over generic equivalent

In addition to any prior authorization requirements, generic medications listed below require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

- Pimecrolimus

References

1. Eucrisa Ointment 2% (crisaborole) [prescribing information]. New York, NY: Pfizer Labs; April 2020.
2. Protopic (tacrolimus) [prescribing information]. Madison, NJ: LEO Pharma Inc.; February 2019.
3. Elidel (pimecrolimus) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2020.
4. Opzelura® (ruxolitinib) [package insert]. Wilmington (DE): Incyte Corporation; 2021 Sep.
5. Weston WL, Howe W. Treatment of atopic dermatitis (eczema). In: Dellavale RP, Levy ML, Fowler J, Corona R (Eds). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 3]. Available from: <http://www.uptodate.com/utd/index/do>.
6. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, 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 Jul;71(1):116-32.
7. Sidbury R, Davis DM, Cohen DE, Cordoro KM, Berger TG, Bergman JN, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014 Aug;71(2):327-49.
8. Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. *J Am Acad Dermatol*. 2014 Dec;71(6):1218-33.
9. Schneider L, Tilles S, Lio P, Boguniewicz M, Beck L, LeBovidge et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013 Feb;131(2):295-9.e1-27.
10. Incyte Corporation. TRuE AD1 - An Efficacy and Safety Study of Ruxolitinib Cream in Adolescents and Adults With Atopic Dermatitis. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2021- [cited 2021 Nov 03]. Available from: [http://clinicaltrials.gov/show/URL of the record NLM Identifier: NCT03745638](http://clinicaltrials.gov/show/URL%20of%20the%20record%20NLM%20Identifier%3A%20NCT03745638).
11. Incyte Corporation. TRuE AD2 - An Efficacy and Safety Study of Ruxolitinib Cream in Adolescents and Adults With Atopic Dermatitis. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2021- [cited 2021 Nov 03]. Available from: [http://clinicaltrials.gov/show/URL of the record NLM Identifier: NCT03745651](http://clinicaltrials.gov/show/URL%20of%20the%20record%20NLM%20Identifier%3A%20NCT03745651).
12. Papp K, Szepietowski JC, Kircik L, Toth D, Eichenfield LF, Leung DYM, et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: Results from 2 phase 3, randomized, double-blind studies. *J Am Acad Dermatol*. 2021 Oct; 85(4):863-872.

Review History

10/01/2020 – Updated MH partial unified formulary; retired ST criteria and switched to PA; added Eucrisa PA criteria, added QL, Effective 1/1/2021

11/17/2021 – Updated and reviewed for Nov P&T; matched MH UPPL for 1/1/2022. No clinical changes.

06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Guideline updated to remove Protopic from the brand preferred over generic list. Effective 08/01/2022.

07/20/22 - Reviewed and updated for July P&T. Added new drug Opzelura® (ruxolitinib) to MH criteria. Effective 9/01/22.



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