

**OPZELURA
(ruxolitinib)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Mild to moderate atopic dermatitis (eczema)
 - a. 18 years of age or older
 - i. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - 1) Topical calcineurin inhibitor (see Appendix I)
 - 2) **ONE** topical corticosteroid (see Appendix II)
 - a. **High** potency topical corticosteroid
 - b. Patients with lesions on face, neck, or skin folds
ONLY: low to medium potency topical corticosteroid
 - b. 12 to 17 years of age
 - i. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - 1) Topical calcineurin inhibitor (see Appendix I)
 - 2) A topical corticosteroid (see Appendix II)
 - ii. Prescriber agrees that treatment will be stopped when signs and symptoms resolve **OR** that the patient will be treated for no longer than 8 weeks at a time
 - c. Documented baseline evaluation of the condition using **ONE** of the following scoring tools:
 - i. Investigator's Static Global Assessment (ISGA) score
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. Eczema Area and Severity Index (EASI)
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. Patient-Oriented Eczema Measure (POEM)
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. Scoring Atopic Dermatitis (SCORAD) index
(e.g., <https://dermnetnz.org/topics/scorad/>)

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- d. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)
- 2. Nonsegmental vitiligo
 - a. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - i. Topical calcineurin inhibitor (see Appendix I)
 - ii. A topical corticosteroid (see Appendix II)
 - b. Other causes of depigmentation (e.g., tinea versicolor, albinism, age spots, melasma, piebaldism, hypopigmented mycosis, pityriasis alba, etc.) have been ruled out

AND ALL of the following for **ALL** indications:

- a. Patient is **NOT** immunocompromised
- b. Prescriber agrees to evaluate patient for latent and active TB infections prior to and during treatment with Opzelura therapy, as appropriate
- c. **NO** active bacterial, invasive fungal, viral, or other opportunistic infections
- d. **NOT** used in combination with potent immunosuppressants, such as azathioprine or cyclosporine
- e. Prescriber has assessed the patient's risk factors for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, etc.) and determined that treatment with Opzelura therapy is appropriate

Prior - Approval Limits

Atopic dermatitis

Quantity 4 tubes
Duration 12 months

Nonsegmental vitiligo

Quantity 12 tubes
Duration 12 months

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

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Diagnoses

Patient must have **ONE** of the following:

1. Atopic dermatitis (eczema)
 - a. Documented improvement using **ONE** of the following scores:
 - i. ISGA – decrease from baseline by at least 2 points
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - ii. EASI – decrease from baseline by at least 75%
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - iii. POEM – decrease from baseline by at least 3 points
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - iv. SCORAD – decrease from baseline by at least 50%
(e.g., <https://dermnetnz.org/topics/scorad/>)
 - b. Prescriber agrees that treatment will be stopped when signs and symptoms resolve **OR** that the patient will be treated for no longer than 8 weeks at a time
 - c. **NO** dual therapy with another Topical Prior Authorization (PA) medication for AD (see Appendix 3)
2. Nonsegmental vitiligo
 - a. Condition has improved or stabilized

AND ALL of the following for **ALL** indications:

- a. Patient is **NOT** immunocompromised
- b. **NO** active bacterial, invasive fungal, viral, or other opportunistic infections
- c. **NOT** used in combination with potent immunosuppressants, such as azathioprine or cyclosporine
- d. Prescriber has assessed the patient's risk factors for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, etc.) and determined that treatment with Opzelura therapy is appropriate

Prior - Approval *Renewal* Limits

Same as above



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Appendix 1

Relative Potency of Topical Calcineurin Inhibitors		
Drug	Dosage Form	Strength
Medium Potency		
Tacrolimus	Ointment	0.1%
Low Potency		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	Dosage Form	Strength
Very high Potency		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, Ointment	0.05%
Diflorasone diacetate	Ointment	0.05%
Flurandrenolide	Tape	4 mcg/cm ²
Halobetasol propionate	Cream, Ointment	0.05%
High Potency		
Amcinonide	Cream, Lotion,	0.1%
Augmented betamethasone dipropionate	Cream, Lotion	0.05%
Betamethasone dipropionate	Cream, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone	Cream, Ointment	0.25%
	Gel	0.05%
Diflorasone diacetate	Cream, Ointment (emollient base)	0.05%
Fluocinonide	Cream, Ointment,	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
Medium Potency		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%
Clocortolone pivalate	Cream	0.1%
Desoximetasone	Cream	0.05%
Fluocinolone acetonide	Cream, Ointment	0.025%
Flurandrenolide	Cream, Ointment,	0.05%



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Fluticasone propionate	Cream	0.05%
	Ointment	0.005%
Hydrocortisone butyrate	Ointment, Solution	0.1%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate	Cream, Ointment,	0.1%
Prednicarbate	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
		0.1%
<i>Low Potency</i>		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion,	0.5%
	Cream, Ointment, Lotion,	1%
	Cream, Ointment,	2.5%
Hydrocortisone acetate	Cream, Ointment	0.5%
	Cream, Ointment	1%

Appendix 3 – List of Topical PA Medications for Atopic Dermatitis (AD)

Generic Name	Brand Name
crisaborole	Eucrisa
roflumilast	Zoryve cream
ruxolitinib	Opzelura
tapinarof	Vtama