

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Ruxolitinib 1.5% Cream (Opzelura)

Notes:

- Quantity Limits: Yes
- ^Adequate trial is defined as the following:
 - Topical corticosteroids – 8 weeks
 - Topical calcineurin inhibitors – 6 weeks
 - Crisaborole (Eucrisa) 2% ointment – 4 weeks
 - Phototherapy – 8 weeks
- Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- *Topical calcineurin inhibitors include tacrolimus (Protopic) 0.03% and 0.1% ointment and pimecrolimus (Elidel) 1% cream. Tacrolimus is the formulary preferred topical calcineurin inhibitor.
 - FDA approved ages:
 - Tacrolimus 0.03% and pimecrolimus 1%: 2 years of age and older. Evidence from clinical trials supports the safe and effective use (off-label) of these products in children younger than 2, including in infants.
 - Tacrolimus 0.1%: 16 years of age and older.
- **Immunocompromised includes immunocompromising diagnosis or current use of immune suppressing medications E.g. biologics, other Janus kinase inhibitors, methotrexate, cyclosporine, azathioprine, or chemotherapy

Initiation (new start) criteria, criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary ruxolitinib (Opzelura) 1.5% cream will be covered on the prescription drug benefit when the following criteria are met:

1. Patient has a diagnosis of mild to moderate atopic dermatitis (percentage of body surface area affected of 3% to 20%)
 - Prescriber is a dermatologist
 - Patient is 12 years of age or older
 - Patient has failed an adequate trial^ of or patient has an allergy/intolerance to the following:
 - At least 2 topical corticosteroids
 - At least 1 topical calcineurin inhibitor*
 - Crisaborole (Eucrisa) 2% ointment (criteria based)
 - Phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient is NOT immunocompromised**

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Revised: 11/10/22
Effective: 01/13/23

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2. Patient has a diagnosis of nonsegmental vitiligo
 - Depigmented areas affect $\geq 0.5\%$ facial body surface area (F-BSA) OR $\geq 3\%$ non-facial BSA
 - Prescriber is a dermatologist
 - Patient is 12 years of age or older
 - Patient has failed an adequate trial[^] of or patient has an allergy/intolerance to the following:
 - At least 1 topical corticosteroid
 - At least 1 topical calcineurin inhibitor*
 - Phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Treatment area does not exceed 10% total BSA
 - Patient is NOT immunocompromised**

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