

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date:	December 8, 2021
Revision Date:	July 7, 2022, October 14, 2022, May 2, 2023, September 19, 2024

Opzelura[®] (ruxolitinib)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 12 years of age.
- Patient must not be immunocompromised or have an active infection.
- The patient must have a documented diagnosis of one of the following:

Mild to moderate atopic dermatitis

- Patient has documented trial and failure of at least two mild-moderate potency topical steroids demonstrated by an inadequate response, intolerance or contraindication to therapy; **AND**
- Patient has documented trial and failure of at least one preferred topical calcineurin inhibitor (Elidel, Protopic) demonstrated by an inadequate response, intolerance or contraindication to therapy; AND
- Patient has documented trial and failure of Eucrisa demonstrated by an inadequate response, intolerance or contraindication to therapy.

Non-segmental vitiligo involving up to 10% of body surface area (BSA)

- Patient has documented trial and failure of at least two moderate to high potency topical steroids demonstrated by an inadequate response, intolerance or contraindication to therapy; **AND**
- Patient has documented trial and failure of at least one preferred topical calcineurin inhibitor (Elidel, Protopic) demonstrated by an inadequate response, intolerance or contraindication to therapy; AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 1.5% topical cream.