

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

## 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**
    - Trial and failure of at least two mild-moderate potency topical steroids. Contraindications, adverse effects and/or intolerance must be documented; **AND**
    - Patient has had a trial of at least one preferred topical calcineurin inhibitor (Elidel, Protopic) and experienced inadequate response or intolerance; **AND**
    - Patient has had a trial and failure of Eucrisa.
  - Non-segmental vitiligo involving up to 10% of body surface area (BSA)**
    - Trial and failure of at least two moderate to high potency topical steroids. Contraindications, adverse effects and/or intolerance must be documented; **AND**
    - Patient has had a trial of at least one preferred topical calcineurin inhibitor (Elidel, Protopic) and experienced inadequate response or intolerance; **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.