ALASKA MEDICAID
Prior Authorization Criteria

Opzelura™ (ruxolitinib)

FDA INDICATIONS AND USAGE[1]

Opzelura™ is a Janus kinase (JAK) inhibitor 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.

APPROVAL CRITERIA[1,2,3]

1. Patient is 12 years of age or older **AND**;
2. Patient has a diagnosis of mild to moderate atopic dermatitis **AND**;
3. Prescribed by or in consultation with a dermatologist **AND**;
4. Patient has had a trial and failure or a contraindication to all the following classes:
    a. Corticosteroids: age ≤ 17 low-mid potency and age ≥ 17 a high potency topical corticosteroid
    b. Topical calcineurin inhibitor (I.E. pimecrolimus or tacrolimus)
    c. Topical phosphodiesterase-4 inhibitor (I.E. crisaborole)

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is immunocompromised **OR**;
3. Being used in combination with therapeutic biologics or other JAK inhibitors **OR**;
4. Patient is taking immunosuppressants such as azathioprine or cyclosporine.

CAUTIONS[1]

- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Regularly monitor patients for infection and manage it promptly.
- Basal cell and squamous cell carcinoma have occurred. Perform periodic skin examinations during treatment and following treatment as appropriate.
- Thrombocytopenia, anemia and neutropenia have occurred. Perform CBC monitoring as clinically indicated.
- Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Janus kinase inhibitors for inflammatory conditions.
- Higher rate of major adverse cardiac events (MACE) (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions.

DURATION OF APPROVAL

- Initial Approval: up to 2 months
- Reauthorization Approval: up to 1 year if the patient has shown disease improvement and/or stabilization and no serious adverse effects

QUANTITY LIMIT

- 4- 60gm tubes per 28 days (60gm per week)

REFERENCES / FOOTNOTES:

1. Opzelura™ [package insert]. Wilmington, DE; Incyte; September 2021.
2. Papp K, Szepietowski J, Kircik L. et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: Results from 2 phase 3, randomized, double-blind studies. Available at: https://www.jaad.org/article/S0190-9622(21)00931-2/fulltext. Accessed December 4, 2021.
3. Eichenfield L, Tom W, Chamlin S, et al. Guidelines of care for the management of atopic dermatitis. Available at: https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis. Accessed December 4, 2021.