Opzelura (ruxolitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Opzelura (ruxolitinib) cream	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Opzelura (ruxolitinib) topical cream for the treatment of atopic dermatitis may be approved if the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Individual has a diagnosis of mild to moderate atopic dermatitis; **AND**
III. Individual has had a trial of and inadequate response or intolerance to one topical corticosteroid; **OR**
    A. Topical corticosteroid use is not acceptable due to the following concomitant clinical conditions:
        1. Individual has atopic dermatitis recalcitrant to topical corticosteroids; **OR**
        2. Individual has atopic dermatitis lesions in sensitive areas (such as face, anogenital area or skin folds); **OR**
        3. Individual has steroid-induced atrophy; **OR**
        4. Individual has history of long-term or uninterrupted topical steroid use;

AND

IV. Individual meets the following:
    A. Daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**
        1. Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:
            a. History of or active malignant or pre-malignant skin conditions; **OR**
            b. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**
            c. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis.

Continuation requests for Opzelura (ruxolitinib) for the treatment of atopic dermatitis may be if approved if the following criterion is met:

I. Treatment with Opzelura has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

Initial requests for Opzelura (ruxolitinib) topical cream for the treatment of vitiligo may be approved if the following criteria are met:

I. Individual is at least 12 years old; **AND**
II. Individual is treating non-segmental vitiligo; **AND**
III. Total body area impacted by vitiligo (facial and non-facial) does not exceed 10% of body surface area (BSA) (NCT04057573); **AND**
IV. Individual meets *one* of the following (A or B) (Eleftheriadou,2022):
    A. Failure of topical pharmacological therapy as indicated by 1 and 2 of the following:
        1. Daily treatment of topical corticosteroids of medium to higher potency for at least twelve (12) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**
            a. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:
                i. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**
                ii. Individual has steroid-induced atrophy; **OR**
                iii. History of long-term or uninterrupted topical steroid use;

        AND

        2. Daily treatment of topical calcineurin inhibitors for twelve (12) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**
            a. Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:
                i. History of or active malignant or pre-malignant skin conditions; **OR**
                ii. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**
                iii. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis

    OR

    B. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated

Continuation requests for Opzelura (ruxolitinib) topical cream for the treatment of vitiligo may be approved if the following criteria are met:

I. Treatment with Opzelura has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to evidence of repigmentation, decrease in disease progression, decrease in affected body surface area, and/or improved quality of life)

Opzelura (ruxolitinib) topical cream may not be approved for the following:

I. In combination with therapeutic biologics; **OR**
II. In combination with other oral or topical JAK-inhibitors; **OR**
III. In combination with potent immunosuppressants such as azathioprine or cyclosporine;

OR

IV. Individual has used depigmentation treatments (such as monobenzone) for the past treatment of vitiligo or other pigmented areas (NCT04057573).

Note:
Opzelura contains a black box warning related to JAK-inhibitors. Opzelura has a black box warning for serious infections that can lead to hospitalization or death, malignancies, higher rate of all-cause mortality, higher rate of major adverse cardiovascular events (MACE), and thrombosis. It is noted that these events have occurred in patients receiving JAK-inhibitors for inflammatory conditions. Serious infections included active tuberculosis, invasive fungal infections, bacterial, viral, and other opportunistic infections. Patients with an active, serious infection should avoid use of Opzelura. Higher rate of all-cause mortality including sudden cardiovascular death and MACE, which also includes sudden cardiovascular death, myocardial infarction, and stroke, were also observed in those using JAK-inhibitors for inflammatory conditions. Lymphoma and other malignancies have also been observed.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.