| Pharmacy Policy Bulletin: J-1155 Opzelura (ruxolitinib) – Commercial and Healthcare Reform | |
|---|---|
| **Number:** J-1155 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>**1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-1155-006 | **Original Date:** 12/01/2021 |
| **Effective Date: 04/25/2025** | **Review Date:** 04/09/2025 |

| | |
|---|---|
| **Drugs Product(s):** | • Opzelura (ruxolitinib) |
| **FDA-Approved Indication(s):** | • Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.<br>• Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. |

| | |
|---|---|
| **Background:** | • Opzelura is the first topical formulation of a Janus kinase (JAK) inhibitor FDA approved for atopic dermatitis and vitiligo.<br><br>**Atopic Dermatitis**<br>• Atopic dermatitis (AD) is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification.<br>• According to the 2023 American Academy of Dermatology (AAD) guidelines, topical corticosteroids are recommended for initial treatment of atopic dermatitis, followed by non-steroid therapies. Non-steroid therapies are particularly useful in selected clinical situations such as recalcitrance to steroids, sensitive areas, steroid-induced atrophy, and avoidance of long-term uninterrupted topical steroid use. Opzelura is recommended to decrease inflammation, provide itching relief, and decrease risk for infections. Opzelura can be used short term to decrease the inflammation and itching of patients with mild to moderate AD.<br>• Tacrolimus, pimecrolimus, and crisaborole are non-steroid therapies for topical treatment of atopic dermatitis. |

- Elidel (pimecrolimus) cream 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **mild-to-moderate** atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
- Protopic (tacrolimus) ointment 0.03% (adults and children 2 years of age and older) and 0.1% (adults and adolescents 16 years of age and older) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **moderate-to-severe** atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

- Severity of AD is defined by the validated Investigator Assessment for Atopic Dermatitis (vIGA-AD):
  0 - Clear: No Inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present
  1 - Almost Clear: Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting
  2 - Mild: Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting
  3 - Moderate: Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present
  4 - Severe: Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present
- Therapeutic failure is defined as failure to achieve at least a two-grade improvement in IGA score.

**Vitiligo**

- Vitiligo is an acquired chronic autoimmune depigmentation disorder which results in a loss of functional melanocytes, affecting 0.5-1% of the population worldwide. The most common form, nonsegmental vitiligo, is symmetrical. It can initially have an acrofacial distribution, but may spread to involve the entire body surface. Segmental vitiligo is unilateral and characterized by rapid stabilization.
- First line options are topical calcineurin inhibitors and/or topical or oral corticosteroids. The use of topical and oral corticosteroids is usually short term given their adverse effect profile. Phototherapy is a commonly used non-drug option and is often used in combination with topical +/- oral drug therapy. Combination interventions are often more effective than monotherapy.

**Table 1. Preferred Topical Corticosteroid Examples**

| High potency | Ultrahigh potency |
|---|---|
| Betamethasone dipropionate 0.05% cream or lotion | Betamethasone dipropionate augmented 0.05% gel or ointment |
| Betamethasone dipropionate augmented 0.05% cream | Clobetasol 0.05% ointment, cream, solution, gel, shampoo |
| Betamethasone valerate 0.1% ointment | Clobetasol propionate 0.05% foam |
| Fluocinonide 0.05% ointment, gel, cream, solution | |

| | |
|---|---|
| Triamcinolone acetonide 0.5% ointment or cream | |

- Prescribing Considerations:
  - The use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.
  - Opzelura should be applied as a thin layer twice daily to affected areas of up to 20% of body surface area (BSA) for atopic dermatitis, or 10% of BSA for vitiligo.
  - Opzelura should be stopped when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve. For vitiligo, satisfactory patient response may require ongoing treatment with Opzelura for more than 24 weeks.
  - For atopic dermatitis, if signs and symptoms do not improve within 8 weeks, patients should be re-examined by their healthcare provider. For vitiligo, patients may require more than 24 weeks of treatment to achieve a satisfactory response. If the patient does not find the repigmentation meaningful after 24 weeks of therapy, the patient should be re-evaluated by their healthcare provider.
  - In February 2021, the FDA mandated new and updated warnings concerning increased risk of major adverse cardiovascular events, malignancy, thrombosis, and mortality with JAK inhibitors used to treat certain serious inflammatory conditions. The FDA has taken the stance that JAK inhibitors potentially have the same serious risks regardless of oral or topical administration. Therefore, the JAK inhibitor black box warning also applies to Opzelura.

## Approval Criteria

**I. Atopic Dermatitis**

**A. Initial Authorization**

When a benefit, coverage of Opzelura may be approved when all of the following criteria are met **(1. through 4.)**:

**1.** The member is 12 years of age or older.

**2.** The member has a diagnosis of atopic dermatitis (ICD-10: L20.9), classified as mild to moderate.

**3.** The prescriber attests that the member has a percentage of body surface area (BSA) [excluding scalp] with AD involvement up to 20%.

**4.** The member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the following plan-preferred generic products **(a. or b.)**:

**a.** topical tacrolimus

**b.** topical pimecrolimus

**B. Reauthorization**

When a benefit, reauthorization of Opzelura may be approved when the following criterion is met **(1.)**:

**1.** The prescriber attests that the member has experienced an improvement or response to therapy.

**II. Vitiligo**

**A. Initial Authorization**

When a benefit, coverage of Opzelura may be approved when all of the following criteria are met **(1. through 4.):**

1. The member is 12 years of age or older.
2. The member has a diagnosis of vitiligo (ICD-10: L80), classified as nonsegmental.
3. The prescriber attests that the member's percentage of body surface area (BSA) with vitiligo involvement does not exceed 10%.
4. The member meets one (1) of the following criteria **(a. or b.):**
   - **a.** The member has experienced therapeutic failure or intolerance to at least one (1) generic, formulary high or ultrahigh potency topical corticosteroid.
   - **b.** The member has vitiligo with facial or anogenital involvement.

**B. Reauthorization**

When a benefit, reauthorization of Opzelura may be approved when the following criterion is met **(1.)**:

1. The prescriber attests that the member has experienced meaningful repigmentation of affected areas.

**III**. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans:
  - Initial Authorization:
    - Atopic Dermatitis: If approved, up to an 8 week authorization may be granted.
    - Vitiligo: If approved, up to a 24 week authorization may be granted.
  - Reauthorization
    - If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
2. Elidel [package insert]. Bridgewater, NJ: Bausch Health US LLC; September 2020.
3. Protopic [package insert]. Madison, NJ: LEO Pharma Inc.; June 2022.
4. Eucrisa [package insert]. New York, NY: Pfizer Labs, Division of Pfizer Inc; April 2023.
5. FiercePharma. Incyte's Jakafi Sister Med Clears FDA for Atopic Dermatitis, but Safety Warning a Heavy Cross to Bear. Available at: https://www.fiercepharma.com/pharma/incyte-s-jakafi-sister-med-clears-fda-for-atopic-dermatitis-but-safety-warning-a-heavy-cross. Accessed September 5, 2024.
6. Sidebury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis with topical therapies management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermato*l. 2023 Jan.

7. Seneschal J, Speeckaert R,wolkerstorfer A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task Force Part 1: towards a new management algorithm. *Eur Acad Dermatol Venereol*. 2023;37:2173–2184.
8. Grimes, P. Vitiligo: Management and prognosis. In: UpToDate, Corona R (Ed), Wolters Kluwer. Accessed: September 6, 2024