Pharmacy Policy Bulletin

Title: Ruxolitinib (Opzelura™)

Policy #: Rx.01.258

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Ruxolitinib (Opzelura™)** as provided under the member's prescription drug benefit.

Description:

Atopic dermatitis is a chronic, pruritic, inflammatory skin disease that occurs most frequently in children but also affects adults. Clinical features of atopic dermatitis include skin dryness, erythema, oozing and crusting, and lichenification. Pruritus is a hallmark of the condition and is responsible for much of the disease burden for patients and their families. Atopic dermatitis is often associated with an elevated serum level of immunoglobulin E (IgE) and a personal or family history of atopy, which describes a group of disorders that includes eczema, asthma, and allergic rhinitis. Topically applied corticosteroids and emollients are the mainstay of therapy for atopic dermatitis.

Vitiligo is a common, acquired, autoimmune, chronic disorder of pigmentation characterized by the development of white macules on the skin due to loss of epidermal melanocytes. Given the contrast between the white patches and areas of normal skin, the disease is most disfiguring in darker skin types and has a profound impact on the quality of life of children and adults. Patients with vitiligo often experience stigmatization, isolation, and low self-esteem. Nonsegmental vitiligo, which is the most common type of vitiligo, has an unpredictable course, and treatment is often challenging.

Ruxolitinib (Opzelura™) is 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. It is also indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Ruxolitinib, a Janus kinase (JAK) inhibitor, inhibits JAK1 and JAK2 which mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. JAK signaling involves recruitment of STATs (signal transducers and activators of transcription) to cytokine receptors, activation and subsequent localization of STATs to the nucleus leading to modulation of gene expression. The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.

Policy:

Atopic Dermatitis

INITIAL CRITERIA Ruxolitinib (Opzelura™) is approved when ALL of the following are met:

1. Diagnosis of mild to moderate atopic dermatitis; and
2. One of the following:
    a. Greater than or equal to 3% body surface area (BSA) involvement; or
    b. Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin); and
3. Member is 12 years of age or older; and
4. Prescribed by or in consultation with one of the following:
    a. Dermatologist; or

    b. Allergist/Immunologist; and
5. Inadequate response or inability to tolerate a minimum 30-day treatment (14-day treatment for topical corticosteroids) to at least TWO of the following:
    a. Medium or high potency topical corticosteroid; or
    b. Pimecrolimus (Elidel) cream; or
    c. Tacrolimus ointment; or
    d. Crisaborole (Eucrisa) cream; and
6. Member is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine); and
7. Opzelura will only be used for short-term and/or non-continuous chronic treatment

Initial authorization duration: 12 weeks

REAUTHORIZATION CRITERIA Ruxolitinib (Opzelura™) is re-approved when ALL of the following are met:

1. Documentation of positive clinical response to therapy as evidenced by at least ONE of the following:
    a. Reduction in body surface area involvement from baseline; or
    b. Reduction in pruritus severity from baseline; or
    c. Improvement in quality of life from baseline; and
2. Member is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine); and
3. Opzelura will only be used for short-term and/or non-continuous chronic treatment

Reauthorization duration: 6 months

Nonsegmental Vitiligo

INITIAL CRITERIA: Ruxolitinib (Opzelura™) is approved when ALL of the following are met:

1. Diagnosis of nonsegmental vitiligo; and
2. Member is 12 years of age or older; and
3. Inadequate response or inability to tolerate at least one of the following:
    a. Medium or higher potency topical corticosteroid; or
    b. Pimecrolimus cream; or
    c. Tacrolimus ointment; and
4. Prescribed by or in consultation with a dermatologist; and
5. Not used in combination with potent immunosuppressant (e.g., azathioprine or cyclosporine) or therapeutic biologics

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Ruxolitinib (Opzelura™) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Not used in combination with potent immunosuppressant (e.g., azathioprine or cyclosporine) or therapeutic biologics

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:
SERIOUS INFECTIONS

Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death and adverse reactions.

Reported infections include:

Active tuberculosis, which may present with pulmonary or extrapulmonary disease.
Invasive fungal infections, including candidiasis and pneumocystosis.
Bacterial, viral, and other infections due to opportunistic pathogens.

Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled.

The risks and benefits of treatment with OPZELURA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OPZELURA.

MORTALITY

Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with oral Janus kinase inhibitors for inflammatory conditions.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions [see Warnings and Precautions.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions.

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis has been observed at an increased incidence in patients treated with oral Janus kinase inhibitors for inflammatory conditions compared to placebo. Many of these adverse reactions were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Atopic dermatitis (eczema): Pathogenesis, clinical manifestations, and diagnosis. UpToDate. October 2022. Available at: https://www.uptodate.com/contents/atopic-dermatitis-eczema-pathogenesis-clinical-manifestations-and-diagnosis?search=atopic%20derm&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2. Accessed February 01, 2023.

Ruxolitinib (Opzelura) [package insert]. Wilmington, DE. Incyte Corporation. January 2023. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=24da5509-6631-4795-9d42-273faecd08e7. Accessed February 01, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Opzelura™	Ruxolitinib

Cross References:

Rx.01.33 Off Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	2.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023
Next Required Review Date:	March 17, 2023