MEDICAL MUTUAL®

Drug Policy

Policy:	Opzelura (ruxolitinib)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023

OVERVIEW

Opzelura, a Janus kinase (JAK) inhibitor, is indicated for the topical short-term and non-continuous treatment of mild to moderate **atopic dermatitis** in patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

POLICY STATEMENT

This policy involves the use of Opzelura. Prior authorization is recommended for pharmacy benefit coverage of Opzelura. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Opzelura as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Opzelura be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Opzelura is recommended in those who meet the following criteria:

1. **Vitiligo**. Approve if the patient meets all the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient has nonsegmental vitiligo; AND
   - **C)** Patient has vitiligo involvement estimated to affect ≤ 10% of the body surface area; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets ALL the following criteria (a, b, and c):
       - **a)** Patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid; AND

         Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.

b) The duration of this topical corticosteroid therapy was at least 12 weeks; AND
Note: Intermittent or continuous use of a topical corticosteroid for at least 12 weeks would meet the requirement.

c) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; OR

ii. Patient is treating vitiligo affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia; AND

E) Patients meets ALL the following (i, ii, and iii):

i. Patient has tried at least one topical calcineurin inhibitor; AND
Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.

ii. This topical calcineurin inhibitor was applied daily for at least 12 weeks; AND

iii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber; AND

F) The medication is prescribed by or in consultation with a dermatologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 6 months

2. Atopic Dermatitis

Approve if the patient meets all the following (A, B, C, D, E, and F):

A) Patient is ≥ 12 years of age; AND

B) Patient has mild to moderate atopic dermatitis, according to the prescriber; AND

C) Patient has atopic dermatitis involvement estimated to affect ≤ 20% of the body surface area; AND

D) Patient meets ONE of the following (i or ii):

i. Patient meets ALL the following criteria (a, b, and c):

a) Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.

b) This topical corticosteroid was applied daily for at least 28 consecutive days; AND

c) Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; OR

ii. Patient is treating atopic dermatitis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia; AND

E) Patients meets ALL of the following (i, ii, and iii):

i. Patient has tried at least one topical calcineurin inhibitor; AND
Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic®, generic) and pimecrolimus cream (Elidel®, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.

ii. This topical calcineurin inhibitor was applied daily for at least 28 consecutive days; AND

iii. Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber; AND

F) The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 8 weeks
B) *Extended Approval:* 8 weeks

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Opzelura has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with a Biologic or with other JAK inhibitors.** Use of Opzelura in combination with therapeutic biologics or other JAK inhibitors is not recommended (see Appendix for examples).[1] Use of biologics or other JAK inhibitors was prohibited during the Opzelura pivotal studies.[2] There are no data evaluating combination use of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.

2. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine). Use of Opzelura in combination with potent immunosuppressants is not recommended.[1] Use of systemic immunosuppressants was prohibited during the Opzelura pivotal studies.[2] There are no data evaluating combination of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.

3. **Alopecia.** Opzelura is not indicated for the treatment of alopecia.[1] A Phase II study involving patients with alopecia areata did not find any significant improvement in hair regrowth with Opzelura 1.5% cream compared with vehicle.[7] Additional data are needed to establish the efficacy and safety of Opzelura in patients with alopecia.

4. **Plaque Psoriasis.** Opzelura is not indicated for the treatment of plaque psoriasis.[1] There are very limited Phase II data regarding the use of Opzelura in patients with plaque psoriasis.[8,9] Additional data are needed to establish the efficacy and safety of Opzelura in patients with plaque psoriasis.

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte Pharmaceuticals; September 2021.
2. Papp K, Szepietowski JC, Sun K, et al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: results from two phase 3, randomized, double-blind studies. *J Am Acad Dermatol*. 2021;85:863-872.
3. Data on file. Opzelura clinical presentation. Incyte Pharmaceuticals; received September 22, 2021.
4. Kim BS, Howell MD, Sun K, et al. Treatment of atopic dermatitis with ruxolitinib cream (JAK1/JAK2 inhibitor) or triamcinolone cream. *J Allergy Clin Immunol*. 2020;145(2):572-582.
5. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. Section 2: management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-132.
6. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013;131:295-299.
7. Olsen EA, Kornacki D, Sun K, et al. Ruxolitinib cream for the treatment of patients with alopecia areata: a 2-part, double-blind, randomized, vehicle-controlled phase 2 study. *J Am Acad Dermatol*. 2020;82(2):412-419.
8. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2021 Jun 7]. Available from: https://clinicaltrials.gov/. Search term: ruxolitinib cream.
9. Punwani N, Scherle P, Flores R, et al. Preliminary clinical activity of a topical JAK1/2 inhibitor in the treatment of psoriasis. *J Am Acad Dermatol*. 2012;67(4):658-664.
10. Rosmarin D, Pandya AG, Lebwohl M, et al. Ruxolitinib cream for the treatment of vitiligo: a randomized, controlled, phase 2 trial. *Lancet*. 2020;396:110-120.
11. Incyte Press Release: Incyte announces positive results from phase 3 TRuE-V program evaluating ruxolitinib cream in patients with vitiligo. Incyte Pharmaceuticals. Available from: https://investor.incyte.com/press-releases/press-releases/2021/Incyte-Announces-Positive-Results-from-Phase-3-TRuE-V-Program-Evaluating-Ruxolitinib-Cream-in-Patients-with-Vitiligo/default.aspx. Accessed on September 27, 2021.