Clinical Policy Title:	ruxolitinib
Policy Number:	RxA.712
Drug(s) Applied:	Opzelura™
Original Policy Date:	12/07/2021
Last Review Date:	07/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Ruxolitinib (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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ruxolitinib (Opzelura™)	Mild to moderate atopic dermatitis in non-immunocompromised patients	Apply a thin layer twice daily to affected areas of up to 20% body surface area. Do not use more than 60 grams per week	60 grams per week

Dosage Forms

- Cream: 1.5% ruxolitinib

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Atopic dermatitis (must meet all)**:**

1. Diagnosis of mild to moderate atopic dermatitis in non-immunocompromised patients;
2. Prescribed by in consultation with a dermatologist or allergist;
3. Age ≥ 12 years;
4. Trial and failure of a 2-week trial of a generic topical corticosteroid (e.g., betamethasone, clobetasol, halobetasol, triamcinolone) or a generic topical macrolide immunosuppressants (e.g., tacrolimus, pimecrolimus);
5. No concomitant use with other topicals or systemic agents for AD;
6. Requested dose does not exceed 60 grams per week.

Approval Duration

Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Mild to moderate atopic dermatitis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy including but not limited to, reduction in itching and scratching;
3. Requested dose does not exceed 60 grams per week.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MACE: Major adverse cardiac events
FDA: Food and Drug Administration
AD: Atopic dermatitis

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
betamethasone	Apply a thin film of 0.05% cream or ointment topically to the affected skin area(s) once daily.	50 g/week (Diprolene cream, ointment, gel); 50 ml/week for no longer than 2 weeks
clioquinol and hydrocortisone (Ala-Quin®)	Apply as a thin layer to the affected areas 2 to 4 times daily or as directed by a physician.	60 grams per week
fluticasone Propionate (Beser; Cutivate)	Apply a thin film to affected area 1 to 2 times daily. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary	Twice daily application

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive

fungal, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase inhibitors for inflammatory conditions.
- Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions.
- Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions.
- 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, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Janus kinase inhibitors for inflammatory conditions.

APPENDIX D: General Information

Use of Opzelura™ in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

References

1. Opzelura™ prescribing information. Wilmington, DE: Incyte Corporation; September 2021 Available at: https://www.opzelura.com/prescribing-information.pdf. Accessed October 12, 2021.
2. Clinical Pharmacology [database online] powered by Clinical Key. Tampa, FL: Elsevier, 2020. Available at: https://www.clinicalkey.com. Accessed October 12, 2021.
3. Betamethasone dipropionate cream prescribing information. Parsippany, NJ: Actavis Pharma, Inc; Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=24da5509-6631-4795-9d42-273faecd08e7&type=display. Accessed October 12, 2021.
4. Lexicomp. [Internet database]. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: https://online.lexi.com . Accessed October 12, 2021
5. upToDate. [Internet database]. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: https://www.uptodate.com/contents/treatment-of-atopic-dermatitis-eczema . Accessed October 13, 2021

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/07/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Trial and failure of a 2-week trial of a generic topical corticosteroid or a generic topical macrolide immunosuppressants (e.g., betamethasone, clobetasol, halobetasol, triamcinolone, tacrolimus, pimecrolimus) to Trial and failure of a 2-week trial of a generic topical corticosteroid (e.g., betamethasone, clobetasol, halobetasol, triamcinolone) or a generic topical macrolide immunosuppressants (e.g., tacrolimus, pimecrolimus). 2. Initial Approval Criteria, I.A.5: Updated to	06/29/2022	07/18/2022

remove prior trial and failure criteria "Requested dose failure of two of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced a. One formulary medium to very high potency corticosteroids, each used for ≥ 2 weeks; b. One non steroidal therapy *: topical calcineurine inhibitor (e.g.,tacrolimus 0.03% ointment and pimecrolimus 1% cream) Or Eurica, each for ≥ 4 weeks; * These agents may require prior authorization.”		