PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

OPZELURA
(ruxolitinib cream)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Atopic Dermatitis
Opzelura is indicated for the 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.

Nonsegmental Vitiligo
Opzelura is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

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

COVERAGE CRITERIA

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 12 years of age or older
- The patient meets ONE of the following:
    - The patient's disease is NOT adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor)
    - Other topical prescription therapies are NOT advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor)
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days

Nonsegmental Vitiligo
Authorization may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine

- The request is for an adult or pediatric patient 12 years of age or older
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days

CONTINUATION OF THERAPY

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL the following criteria are met:
- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 12 years of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days

Nonsegmental Vitiligo
Authorization may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL the following criteria are met:
- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine
- The request is for an adult or pediatric patient 12 years of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days

QUANTITY LIMITS APPLY
60 grams per 21 days* or 180 grams per 63 days**
For larger BSA for Vitiligo: 180 grams per 21 days* or 540 grams per 63 days**
For larger BSA for Atopic Dermatitis: 240 grams per 21 days* or 720 grams per 63 days**
**The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*
The intent is for prescriptions of the requested drug to be filled one month at a time for new starts; there should be no 3-month supplies filled for new starts.

DURATION OF APPROVAL (DOA)
- 5018-C:
  - Nonsegmental Vitiligo: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
  - Atopic Dermatitis: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed February 13, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/13/2024).

4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014; 70:338-51.
5. Eichenfield LF, Tom WL, 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; 71:116-32.
6. Papp K, Szepietowski JC, Kircik L, et. al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: Results from 2 phase 3, randomized, double-blind studies. *J Am Acad Dermatol* 2021;85:863-72.
7. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. February 12, 2024. Available at: https://chemm.hhs.gov/burns.htm. Accessed February 13, 2024.
8. Kubelis-López DE, Zapata-Salazar NA, et al. Updates and new medical treatments for vitiligo (Review). Exp Ther Med. 2021;22(2):797.
9. Eleftheriadou V, Atkar R, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. The British Journal of Dermatology. 2021;186(1):18-29.
10. U.S. Food & Drug Administration. FDA approves topical treatment addressing repigmentation in vitiligo in patients age 12 and older. July 19, 2022. Available at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-topical-treatment-addressing-repigmentation-vitiligo-patients-aged-12-and-older. Accessed February 22, 2024.
11. Felsten, LM, Alikhan A, Pretronic-Rosic V. Vitiligo: a comprehensive overview. *J Am Acad Dermatol* 2011; 65 (3): 493-514.
12. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023: 89(1): e1-e20.