Reference number(s)
7052-E

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit

Opzelura

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Opzelura	ruxolitinib	cream

Indications

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 2 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.

Limitations of Use

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

Initial Step Therapy with Quantity Limit

Include Prescription (Rx) and Over-the-counter (OTC) products unless otherwise stated.

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then a quantity limit will apply. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a PA is required.

Initial Limit Quantity

The duration of 21 days is used for a 28-day fill period and 63 days is used for a 84-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Opzelura (ruxolitinib)	60 grams / 21 days	180 grams / 63 days

Table 1: Examples of Topical Corticosteroids for Treatment of Atopic Dermatitis [2,3,4]

Potency	Drug
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
Medium Potency	betamethasone valerate cream/lotion 0.1%/foam 0.12%
Medium Potency	clocortolone pivalate cream 0.1%
Medium Potency	desonide lotion, ointment 0.05%
Medium Potency	desoximetasone cream 0.05%
Medium Potency	fluocinolone acetonide cream/ointment/kit 0.025%
Medium Potency	flurandrenolide cream/ointment/lotion 0.05%

Potency	Drug
Medium Potency	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
Medium Potency	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
Medium Potency	hydrocortisone probutate cream 0.1%
Medium Potency	hydrocortisone valerate cream/ointment 0.2%
Medium Potency	mometasone furoate cream/lotion/solution 0.1%
Medium Potency	prednicarbate cream/ointment 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion 0.025%
Medium Potency	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
High Potency	betamethasone dipropionate cream/ointment 0.05%
High Potency	betamethasone dipropionate augmented cream/lotion 0.05%
High Potency	betamethasone valerate ointment 0.1%
High Potency	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%
High Potency	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
High Potency	halcinonide cream/ointment 0.1%
High Potency	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%
High Potency	mometasone furoate ointment 0.1%
High Potency	triamcinolone acetonide aerosol solution 0.147 mg/g
High Potency	triamcinolone acetonide cream/ointment 0.5%
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
Very High Potency	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
Very High Potency	diflorasone diacetate ointment 0.05%
Very High Potency	flurandrenolide tape 4mcg/cm2
Very High Potency	halobetasol propionate cream/ointment/lotion/kit 0.05%
Very High Potency	fluocinonide cream 0.1%

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 of 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 2 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 of 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 of 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 2 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 of 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 body surface area (BSA) for Vitiligo: 180 grams per 21 days or 540 grams per 63 days.

For larger body surface area (BSA) for Atopic Dermatitis: Pediatric patients 2 to 11 years of age: 120 grams per 21 days or 360 grams per 63 days.

For larger body surface area (BSA) for Atopic Dermatitis: Patients 12 years of age and older: 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)

- 7052-E:
  - 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 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed June 20, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/20/2025).
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. December 26, 2024. Available at: https://chemm.hhs.gov/burns.htm. Accessed June 20, 2025.
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 June 20, 2025.
11. Felsten, LM, Alikhan A, Pretronic-Rosic V. Vitiligo: a comprehensive overview Part II: treatment options and approach to treatment. 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.