AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Opzelura	Page:	1 of 4
Effective Date:	7/30/2025	Last Review Date:	
Applies to:	☒ Illinois ☒ Florida Kids	☒ New Jersey ☒ Pennsylvania Kids	☒ Maryland ☐ Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Opzelura under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

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

Applicable Drug List:

Opzelura

Policy/Guideline:

Criteria for Initial Approval:
For the indication of Atopic Dermatitis, the patient is unable to take the required formulary alternatives, Rinvoq and Eucrisa, due to a trial and inadequate treatment response, or intolerance, or a contraindication

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.

Approval Duration and Quantity Restrictions:

- Nonsegmental Vitiligo
  Initial therapy: 7 months
  Continuation of therapy: 12 months

- Atopic Dermatitis
  Initial therapy: 3 months
  Continuation of therapy: 12 months

Quantity Level Limit:
- 60 grams per 21 days
- For larger body surface area (BSA) for Vitiligo: 180 grams per 30 days.
- For larger body surface area (BSA) for Atopic Dermatitis: 240 grams per 30 days

References:

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; August 2024.
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.