JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS141
		Effective Date	01/19/2022
		Review Date	10/19/2022
	Subject **Opzelura**	*Revision Date*	10/19/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Opzelura

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I. POLICY

A. Opzelura (ruxolitinib) cream will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Opzelura** may be approved for patients who meet the following:
   1. Atopic Dermatitis (AD)
      a. Patient is 12 years of age or older
      b. Documentation has been provided showing a diagnosis of mild to moderate atopic dermatitis
      c. Documentation has been provided showing Opzelura will be used for short-term treatment
      d. Patient has an affected Body Surface Area (BSA) of 3% to 20%
      e. Documentation has been provided showing a baseline assessment using one of the following tools:
         I. Investigator's Static Global Assessment (ISGA) score
         II. Eczema Area and Severity Index (EASI)
         III. Patient-Oriented Eczema Measure (POEM)
         IV. Scoring Atopic Dermatitis (SCORAD) index
      f. Documentation has been provided showing trial and inadequate response, or contraindication to all of the following:
         I. One or more formulary topical corticosteroids
         II. One topical calcineurin inhibitor (pimecrolimus [Elidel] or tacrolimus [Protopic])
         III. Eucrisa (crisaborole)
      g. Prescriber is, or has consulted with, an allergist, immunologist, or dermatologist
   2. Vitiligo
      a. Patient is 12 years of age or older
      b. Documentation has ben provided showing a diagnosis of nonsegmental vitiligo

c. Patient has an affected BSA ≤ 10%
d. Documentation has been provided showing trial and inadequate response, or contraindication to both of the following:
   I. One or more formulary topical corticosteroids
   II. One topical calcineurin inhibitor (pimecrolimus [Elidel] or tacrolimus [Protopic])
e. Prescriber is, or has consulted with a dermatologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approvals and additional guidance by Indication:
   1. AD:
      a. Approval will be limited to 8 weeks of therapy
      b. If a clinical improvement is not seen after 8 weeks of treatment, the patient should be re-evaluated by a provider. Opzelura is not FDA-approved for continuous use in treating AD.
   2. Vitiligo:
      a. Initial Approval will be limited to 6 months of therapy
      b. If a clinical improvement is not seen after 6 months of treatment, the patient should be re-evaluated by a provider.
      c. Continuation of therapy for treatment of Vitiligo may be approved in 12-month intervals with documentation that the patient has experienced meaningful repigmentation as a result of treatment
B. Limitation: Opzelura cream is limited to one 60-gram tube per week.

IV. EXCLUSIONS

A. Opzelura will not be approved for the following:
   1. Patients that are less than 12 years of age
   2. Patients that are immunocompromised
   3. Patients with an active, serious infection, including localized infections
   4. Patients with active hepatitis B or hepatitis C infection
   5. Long-term, continuous treatment for AD
   6. Concurrent use with biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine
   7. Any indications or uses that are not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Opzelura [Prescribing Information]. Wilmington, DE: Incyte Corporation; July 2022.
2. 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 Jul;71(1):116-32.
3. Chang HC, Hsu YP, Huang YC. The effectiveness of topical calcineurin inhibitors compared with topical corticosteroids in the treatment of vitiligo: A systematic review and meta-analysis. J Am Acad Dermatol. 2020;82(1):243

VI. APPROVALS

Signature on file at JHHC

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DATE OF REVISION	SUMMARY OF CHANGE
01/19/2022	Policy Creation
10/19/2022	Added criteria for vitiligo as a new FDA-approved indication

Review Date: 01/19/2022, 10/19/2022

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