STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202		GPI-10 (9027206050)	ROUTE ≠ ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is NOT immunocompromised
   - The patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (e.g., pimecrolimus, tacrolimus)

   If yes, continue to #2.
   If no, continue to #3.

2. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., pimecrolimus, tacrolimus, Eucrisa)
   - Systemic therapeutic biologics (e.g., Dupixent) or other JAK inhibitors (e.g., Rinvoq)
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial at the end of the guideline.

   If no, **approve for 3 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days**.

3. Does the patient have a diagnosis of nonsegmental vitiligo **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text on the next page.

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. **If you have mild to moderate atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. You are NOT immunocompromised (low immune system)
   3. You had a trial of or contraindication (harmful for) to a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) OR a topical non-steroidal immunomodulating agent (such as pimecrolimus, tacrolimus)
   4. You are NOT using Opzelura together with ANY of the following:
      a. Other non-steroidal topicals (such as tacrolimus, pimecrolimus, Eucrisa)
      b. Systemic therapeutic biologics (such as Dupixent) or other JAK inhibitors (such as Rinvoq)
      c. Potent immunosuppressants (such as azathioprine, cyclosporine)

C. **If you have nonsegmental vitiligo, approval also requires:**
   1. You are 12 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of vitiligo, please refer to the Initial Criteria Section.

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA (CONTINUED)

2. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., pimecrolimus, tacrolimus, Eucrisa)
   - Systemic therapeutic biologics (e.g., Dupixent) or other JAK inhibitors (e.g., Rinvoq)
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, or facial/interdigital (between the fingers or toes) involvement
   C. You are NOT using Opzelura together with ANY of the following:
      1. Other non-steroidal topicals (such as tacrolimus, pimecrolimus, Eucrisa)
      2. Systemic therapeutic biologics (such as Dupixent) or other JAK inhibitors (such as Rinvoq)
      3. Potent immunosuppressants (such as azathioprine, cyclosporine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES
- Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corp., July 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22

Created: 09/21
Client Approval: 09/22

P&T Approval: 04/22