

Ruxolitinib (OPZELURA) Cream in Nonsegmental Vitiligo

Criteria for Use

June 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive topical ruxolitinib cream.

- Active, serious, systemic or localized infection, including undrained abscess (however, ruxolitinib cream may be started / restarted once the infection is controlled).
- Untreated latent or active tuberculosis infection. (Pretreatment TB screening is not recommended but should be considered. Safety of this drug is unknown in patients with current or past tuberculosis.)
- Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.¹ Ruxolitinib may be initiated after starting antiviral prophylaxis.² (Consider HBV screening. Safety of this drug is unknown in patients with current or past HBV infection.)
- HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.¹ Ruxolitinib may be initiated after starting HBV antiviral prophylaxis.² (Safety is unknown with current or past HBV infection.)
- Active hepatitis C. (Consider HCV screening. Safety of this drug is unknown in patients with current or past HCV infection.)
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with ruxolitinib cream. (Safety of this drug is unknown in patients with HIV seropositivity.)
- Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical unless the treating dermatologist and oncologist agree that risk-benefits favor using the drug.
- At increased risk of thrombosis or major adverse cardiovascular events where potential harms are expected to outweigh the anticipated benefits. (Safety of this drug is unknown in patients with history of thrombosis.)
- Concomitant use with therapeutic (immunomodulatory) biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- Concomitant use with strong CYP3A4 inhibitors
- Breastfeeding (during treatment and for about 4 weeks after the last dose)

Inclusion Criteria

All of the following criteria must be met.

- Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated expert.
- Diagnosis of nonsegmental vitiligo.
- Application of ruxolitinib cream is intended for $\leq 10\%$ of total body surface area.
- Tried and had an inadequate response or intolerance to **topical corticosteroids and topical calcineurin inhibitors** unless medically inadvisable. An adequate trial is ≥ 6 months of adherence to prescribed regimens.
- Tried and had an inadequate response or intolerance to **phototherapy**³ unless medically inadvisable, not available or not feasible.

Vitiligo is NOT a cosmetic condition. The Directive 1108.08 policy on Cosmetic and Enhancement Drugs does NOT apply.

Additional Inclusion Criteria

Select if appropriate.

- For patients due for vaccinations: Immunizations have been updated, particularly for herpes zoster.⁴
- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy.

Other Justification

Footnotes

- 1 Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.
- 2 Consult a hepatologist or infectious diseases expert for advice on whether to start antiviral prophylaxis to prevent HBV reactivation.
- 3 Phototherapy was excluded in clinical trials. The safety and efficacy of combination phototherapy + topical ruxolitinib are unknown.
- 4 When possible, vaccinations should be updated before the patient initiates topical ruxolitinib. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with topical ruxolitinib, preferably at times when a robust immune response to vaccination can be expected.

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