

Risankizumab-rzaa (SKYRIZI) in Psoriatic Arthritis

Criteria for Use

August 2022

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. Also refer to the [Psoriasis and Psoriatic Arthritis Treatment Guide](#) available at the [PBM INTRANet](#).

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive risankizumab-rzaa.

- Active, serious, systemic or localized infection, including undrained abscess (however, risankizumab-rzaa may be started / restarted once the infection is controlled).
- Untreated latent or active tuberculosis infection.
- Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.¹ Risankizumab-rzaa may be initiated after starting antiviral prophylaxis.
- HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.¹ Risankizumab-rzaa may be initiated after starting antiviral prophylaxis.²
- Untreated HIV infection or at high risk for HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with risankizumab-rzaa.
- Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of risankizumab-rzaa.

Inclusion Criteria

All of the following criteria must be met:

- Risankizumab-rzaa is prescribed and monitored by a VA / VA Community Care rheumatologist, dermatologist, or locally designated psoriasis expert.
- Risankizumab-rzaa is prescribed **at the FDA-approved dose for psoriatic arthritis**.
- Has inflammatory** articular disease (joint, spine, and/or enthesal) and a definite or provisional diagnosis of **psoriatic arthritis**. (Risankizumab-rzaa is ineffective for ankylosing spondylitis and is unlikely to be effective for axial PsA.)
- Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].

- Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).³
- Current or past completion of hepatitis C screening. Risankizumab-rzaa may be initiated while waiting for test results.
- ONE tumor necrosis factor inhibitor (TNFI)** is medically inadvisable, not tolerated, or not adequate (i.e., NO or partial response after 12 weeks or loss of initial response).
- ONE interleukin-17A inhibitor (IL-17AI; i.e., ixekizumab [preferred] or secukinumab)** is medically inadvisable, not tolerated or not adequate (i.e., NO response after 12 weeks, inadequate partial response after 24 weeks, or loss of initial response).

Additional Inclusion Criteria

Select if applicable.

- 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.

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 Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers ≥ 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for risankizumab-rzaa.

Section	Criterion	Issues for Consideration
Exclusion Criteria	HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis. ¹ Risankizumab-rzaa may be initiated after starting antiviral prophylaxis. ²	<p>In patients who are HBsAg-negative but anti-HBc-positive, the presence of antibody to hepatitis B surface antigen (antiHBs) does not guarantee protection against HBV reactivation, and the available evidence is insufficient to support the use of anti-HBs titers in deciding whether to give antiviral prophylaxis.*</p> <p>Consultation with a local hepatologist or infectious diseases expert is recommended to advise on whether to initiate prophylactic antiviral therapy or perform preemptive monitoring with deferred prophylactic therapy.</p> <p>* Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. <i>Gastroenterology</i>. 2015;148(1):215–219. DOI:https://doi.org/10.1053/j.gastro.2014.10.039</p>
Inclusion Criteria	Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).	Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers ≥ 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).
	Tumor necrosis factor inhibitor (TNFI) therapy is medically inadvisable....	TNFI may be medically inadvisable for reasons that include but are not limited to heart failure, demyelinating disease, multiple sclerosis in first-degree relative, lupus, recurrent infections, serious infections, etc.
	Interleukin-17A inhibitor (i.e., ixekizumab [preferred] or secukinumab) is medically inadvisable....	IL-17A inhibitors may be medically inadvisable for reasons that include but are not limited to Crohn's disease, ulcerative colitis, or recurrent or severe Candida infections.
	Ustekinumab is medically inadvisable....	<p>Ustekinumab may be medically inadvisable for reasons that include but are not limited to history of noninfectious pneumonia (e.g., interstitial pneumonia, eosinophilic pneumonia, cryptogenic organizing pneumonia) and <u>severe</u> plaque psoriasis (i.e., risankizumab-rzaa preferred).</p> <p>Ustekinumab 45 mg is preferred for psoriatic arthritis with concomitant psoriasis in patients weighing ≤ 100 kg and for psoriatic arthritis without psoriasis. Cost-benefit is lost with ustekinumab 90 mg.</p> <p>Ustekinumab and the IL-23 inhibitors (guselkumab and risankizumab-rzaa) are ineffective for <u>axial</u> psoriatic arthritis.</p>

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