Risankizumab-rzaa (SKYRIZI) in Plaque Psoriasis
Criteria for Use
March 2024

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.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for 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. Risankizumab-rzaa may be initiated after starting antiviral prophylaxis. [1, 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 dermatologist or locally designated psoriasis expert.
- ☐ Risankizumab-rzaa is prescribed at the FDA-approved dose for plaque psoriasis.
- ☐ Chronic (≥ 6 months) moderate to severe plaque psoriasis (including involvement of nails only).
- ☐ 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.
- ☐ Methotrexate monotherapy is medically inadvisable, not tolerated, or not adequate.
- ☐ Phototherapy is medically inadvisable, inadequate, not available or not feasible.
- ☐ Tumor necrosis factor inhibitor (TNFI) is medically inadvisable, not tolerated or not adequate. [4]

☐ Interleukin-17A inhibitor (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 appropriate.

☐ If HBsAg-negative but anti-HBc-positive, a GI / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.

☐ 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.

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 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).

4 Example: NO response after 12 weeks with ONE TNFI; inadequate partial response after 12-week therapeutic trials of TWO TNFIs for a total of 24 weeks; or loss of initial response).

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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]	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.* 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. * Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. Gastroenterology. 2015;148(1):215–219. DOI:https://doi.org/10.1053/j.gastro.2014.10.039
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.
	Methotrexate monotherapy is medically inadvisable, not tolerated, or not adequate.	Refer to *Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders* under Clinical Recommendations at PBM INTRAnet. Inadequate response to methotrexate refers to NO treatment benefit after 3 months, of which at least 2 months is at the standard target dose; or inadequate partial response after 6 months. **Target Doses**: Methotrexate: 15–25 mg ONCE WEEKLY orally, subcutaneously, or intramuscularly. Use lower doses if limited by toxicity.
	Phototherapy is medically inadvisable, inadequate….	Reasons for phototherapy being "medically inadvisable" include (and are not limited to) *CONFIRMED (preferably by a written biopsy report)* history of skin cancer, melanoma or strong likelihood of developing them (e.g., Fitzpatrick skin type I or II = pale skin, easily sunburns). Inadequate phototherapy refers to NO treatment benefit after 12 treatments or inadequate partial response after 24 treatments.
	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….	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 severe plaque psoriasis (i.e., risankizumab-rzaa preferred).

Revisions:

- March 2024. Removed ustekinumab prerequisite.
- February 2022. Removed HCV exclusion criterion; removed malignancy exclusion (to be consistent with the prescribing information); added "total" before anti-HBc under inclusion criteria; changed inclusion criterion from "Completed HCV screening" to "Current or past completion of HCV screening…"; added footnote 2; added Supplemental Information section; moved selected footnotes to Supplemental Information; added risankizumab-rzaa preferred over ustekinumab for severe plaque psoriasis; added pregnancy-related inclusion criteria.

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