Upadacitinib (RINVOQ) in Psoriatic Arthritis
Criteria for Use
June 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 see the *Rheumatoid Arthritis Treatment Guide* at *PBM INTRAnet*.

NOTE: Tofacitinib is the preferred JAK inhibitor in new starts for psoriatic arthritis.

Exclusion Criteria

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

- ☐ Active, serious, systemic or localized infection, including undrained abscess (however, upadacitinib 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] Upadacitinib 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] Upadacitinib may be initiated after starting antiviral prophylaxis.[2]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with upadacitinib.
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer.
- ☐ At increased risk of thrombosis or major adverse cardiovascular events where potential harms are expected to outweigh the anticipated benefits.
- ☐ Lymphocytes < 500 cells/mm^3 confirmed by repeat testing, neutrophils < 1000 cells/mm^3, or hemoglobin < 8 g/dL. (Upadacitinib may be started / restarted once the lymphopenia, neutropenia and/or anemia resolve.)
- ☐ Severe hepatic impairment (Child-Pugh class C).
- ☐ Concomitant therapy with biologic disease-modifying antirheumatic drugs (bDMARDs), other immunosuppressive biologics or potent immunosuppressants (e.g., azathioprine, cyclosporine, tacrolimus).[3]
- ☐ Concomitant therapy with strong CYP3A4 inducers (e.g., rifampin).
- ☐ Pregnancy.
- ☐ Breastfeeding.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of upadacitinib therapy.[4]

Inclusion Criteria

ALL of the following criteria must be fulfilled.

- ☐ Prescribed[5] and monitored by a VA/VA Community Care rheumatologist, dermatologist, or locally designated expert.
- ☐ Has **inflammatory articular disease** (joint, spine, and/or entheseal) and a definite or provisional diagnosis of **active psoriatic arthritis.**
- ☐ 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]).
- ☐ Current or past completion of hepatitis C screening. (Upadacitinib may be initiated while waiting for test results.).
- ☐ **ONE tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated, or not adequate after 3 months.

Additional Inclusion Criteria

- ☐ 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. Except overlaps during treatment transition.
4. When possible, vaccinations should be updated before the patient initiates upadacitinib. Unless contraindicated, recombinant zoster (SHINGRIX equivalent) vaccine should be completed or at least initiated by the end of the first year of treatment with upadacitinib, preferably when upadacitinib dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
5. Prescribe at the FDA-recommended dose for psoriatic arthritis, adjusting for CYP3A4 drug interactions, severe renal impairment, and hematocytopenias.

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for upadacitinib.

Section	Criterion	Issues for Consideration
Exclusion Criteria	HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive. Upadacitinib may be initiated after starting antiviral prophylaxis[1] or a locally designated hepatologist or infectious diseases expert approves proceeding without antiviral prophylaxis.	In patients who are HBsAg-negative but anti-HBc-positive, the presence of antibody to hepatitis B surface antigen (anti-HBs) 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).
	ONE tumor necrosis factor inhibitor (TNFI) 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. Aversity to injections or barriers to in-clinic administration (e.g., travel) should be adjudicated case by case as a reason why TNFI is medically inadvisable.
	ONE interleukin-17A inhibitor (IL-17AI) (ixekizumab preferred) is medically inadvisable….	IL-17AI may be medically inadvisable for reasons that include but are not limited to inflammatory bowel disease (IBD). IL-17AIs can worsen or cause IBD and should be used with caution. IL-17AIs may be less preferred than other agents approved for IBD and PsA such as ustekinumab and TNFI monoclonal antibodies in patients with IBD.
	Ustekinumab is medically inadvisable….	Ustekinumab may be medically inadvisable for reasons that include but are not limited to axial psoriatic arthritis (ustekinumab is ineffective for ankylosing spondylitis).

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