Tofacitinib (XELJANZ) in Psoriatic Arthritis
Criteria for Use
July 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.

Exclusion Criteria

If ANY of the following criteria are met, the patient should NOT receive tofacitinib.

- ☐ Active, serious, systemic or localized infection, including undrained abscess (however, tofacitinib may be started / restarted once the infection is controlled).[1]
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.[2] Tofacitinib may be initiated after starting antiviral prophylaxis.
- ☐ HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.[2] Tofacitinib may be initiated after starting antiviral prophylaxis.[3]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with tofacitinib.
- ☐ 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, neutrophils < 1000 cells/mm^3, or hemoglobin < 9 g/dL. (Tofacitinib 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, potent immunosuppressants (e.g., azathioprine, cyclosporine, tacrolimus), or strong CYP3A4 inducers (e.g., rifampin).[4]
- ☐ Pregnancy and females of reproductive potential not using adequate contraception.
- ☐ Breastfeeding, unless breastfeeding occurs at least 18 hours after the most recent dose of tofacitinib.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of tofacitinib therapy.

Inclusion Criteria for Psoriatic Arthritis

ALL of the following criteria must be fulfilled.

- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist, dermatologist, or locally designated expert.
- ☐ Tofacitinib is prescribed at the FDA-recommended dose for psoriatic arthritis, adjusting for CYP3A4 drug interactions, moderate or severe renal impairment, moderate hepatic impairment, and hematocytopenias.
- ☐ 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 anti-HBs).
- ☐ Current or past completion of hepatitis C screening. (Tofacitinib may be initiated while waiting for test results.)
- ☐ **ONE tumor necrosis factor inhibitor (TNFI)** is medically inadvisable, not tolerated, or not adequate after 3 months.

Footnotes

1. Use with extreme caution in people 65 years or older due to higher risks of serious infections, fatal infection and possibly increased mortality.
2. **Antiviral prophylaxis for HBV**: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.
3. Consult a hepatologist or infectious diseases expert for advice on whether to start antiviral prophylaxis to prevent HBV reactivation.
4. Except overlaps during treatment transition.

Supplemental Information

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

Section	Criterion	Issues for Consideration
Exclusion Criteria	HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not cleared by a hepatologist or infectious diseases expert.[1]	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
	Lymphocytes < 500 cells/mm^3, neutrophils < 1000 cells/mm^3, or hemoglobin < 9 g/dL (tofacitinib may be started / restarted once the lymphopenia, neutropenia and/or anemia resolve).	**Lymphocyte** count less than 500 cells/mm^3 confirmed by repeat testing; absolute **neutrophil** count less than 1000 cells/mm^3 before initiation of therapy or less than 500 cells/mm^3 during therapy; **hemoglobin** less than 9 g/dL before initiation of therapy or hemoglobin less than 8 g/dL or decrease of more than 2 g/dL during therapy.
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) 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.

Revised:

- July 2022. Separated composite CFU by individual indications for Cerner purposes. Removed requirements for prior IL-17AI and ustekinumab in psoriatic arthritis.
- December 2021. Removed HCV exclusion criterion; changed inclusion criterion from *completed HCV screening* to *current or past completion of HCV screening*; moved selected footnotes to Supplemental Information. Incorporated December 2021 Boxed Warning and Warnings and Precautions regarding mortality, malignancy, MACE, and thrombosis.
- May 2020. Added pregnancy exclusion and updated infection screening.
- March 2020. Incorporates FDA prescribing information and 31 Oct 2019 EMA PRAC provisional recommendations regarding risks of pulmonary embolism and all-cause mortality.

Contact: Francine Goodman, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 12PBM