# Tofacitinib (XELJANZ) in Rheumatoid Arthritis
# Criteria for Use
# October 2025

**VA Pharmacy Benefits Management Services and National Formulary Committee**

*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 tofacitinib.

- ☐ Uncontrolled active infection (however, tofacitinib may be started / restarted once treatment for the infection is initiated).[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.
- ☐ Congenital or acquired immunodeficiency.
- ☐ Malignancy in the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer unless it is documented that the treating rheumatologist 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.
- ☐ 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.
- ☐ 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

ALL of the following criteria must be fulfilled.

- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist or locally designated expert.
- ☐ Moderate to severe active **rheumatoid arthritis.**
- ☐ Tofacitinib is prescribed at the FDA-recommended dose for rheumatoid arthritis, adjusting for CYP3A4 drug interactions, moderate or severe renal impairment, moderate hepatic impairment, and hematocytopenias.
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^3
- ☐ 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. (Tofacitinib may be initiated while waiting for test results.)
- ☐ **Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated, not adequate (i.e., NO response to ONE TNFI after 3 months, partial response to 3-month trials of TWO TNFIs = total 6 months), or lost response.

## Additional Inclusion Criteria

Select if applicable.

## Other Justification

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## 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. When possible, vaccinations should be updated before the patient initiates tofacitinib. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with tofacitinib, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.

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Contact: Francine Goodman, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)