Tofacitinib (XELJANZ) in Ankylosing Spondylitis
Criteria for Use
November 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 criteria are met, the patient should NOT receive 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.
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with tofacitinib.
- ☐ Congenital or acquired immunodeficiency.
- ☐ Malignancy within 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).^3
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of tofacitinib therapy.[5]
- ☐ Pregnancy
- ☐ Breastfeeding

Inclusion Criteria

All of the following criteria must be met:

- ☐ Prescribed^4 and monitored by a VA/VA Community Care rheumatologist or locally designated expert.
- ☐ Definite or provisional diagnosis of active ankylosing spondylitis (or radiographic axial spondyloarthritis)
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^5
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].^6
- ☐ Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and anti-HBs).^6
- ☐ Current or past completion of hepatitis C screening. (Tofacitinib may be initiated while waiting for test results.)^6
- ☐ **ONE tumor necrosis factor inhibitor (TNFI)** is medically inadvisable, not tolerated, not adequate after 3 months, or lost response.^7

Additional Inclusion Criteria

Select if applicable.

- ☐ If HBsAg-negative but anti-HBc-positive and consult is deemed indicated: A GI/liver or infectious diseases expert has been (e-)consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.
- ☐ For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

Other Justification

- ☐ _____

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

[6] Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.

[7] Applies only to new starts for tofacitinib. Patients on tofacitinib who are stable (responded after 16 weeks and/or controlled on maintenance therapy) should not be switched to a criteria-required prior drug for nonmedical reasons.

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