

Ixekizumab (TALTZ) 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 are selected, the patient will NOT meet criteria for ixekizumab.

- Uncontrolled, active, severe infection, including undrained abscess (however, ixekizumab may be started/restarted once treatment for the infection is initiated).
- Untreated latent or active tuberculosis infection.
- Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.^1 Ixekizumab may be initiated after starting antiviral prophylaxis.
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with ixekizumab.
- Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of ixekizumab.^2

Inclusion Criteria

All the following must be selected to meet criteria.

- Ixekizumab is prescribed and monitored by a VA/VA Community Care rheumatologist or locally designated expert.
- Ixekizumab is prescribed at the FDA-approved dose for ankylosing spondylitis.
- Has a definite or provisional diagnosis of **active ankylosing spondylitis (or radiographic axial spondyloarthritis)**.
- Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- Completed hepatitis B screening (HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).
- Current or past completion of hepatitis C screening. Ixekizumab may be initiated while waiting for test results.
- Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated or not adequate (i.e., NO or partial response after 3 months or loss of initial response).^3

Additional Inclusion Criteria

Select if applicable.

- If HBsAg-negative but anti-HBc-positive and patient's practitioner deems consult is indicated, a GI/liver or ID 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.

Abbreviations: GI, gastrointestinal; ID, infectious diseases

Other Justification

Footnotes

- ¹ Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used
- ² When possible, vaccinations should be updated before the patient initiates ixekizumab. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with ixekizumab, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
- ³ Applies only to new starts on ixekizumab. Patients on ixekizumab who are stable should not be switched to a criteria-required prior drug for nonmedical reasons.

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