Bimekizumab-bkzx (BIMZELX) in Nonradiographic Axial Spondyloarthritis
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 bimekizumab-bkzx.

- ☐ History of **severe or untreated** depression or suicidal ideation or behavior or risk factors for suicide (e.g., depression, bipolar disorder) – relative contraindication, when potential risks outweigh benefits
- ☐ Uncontrolled active infection, including undrained abscess and fungal infection; however, bimekizumab-bkzx 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 Bimekizumab-bkzx may be initiated after starting antiviral prophylaxis.
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with bimekizumab-bkzx.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 4 weeks before initiation of bimekizumab-bkzx.^2
- ☐ Concomitant treatment with natalizumab or other drugs that have a contraindicated drug interaction (e.g., Bacillus Calmette-Guerin [BCG] vaccine) unless risk-benefits favor use
- ☐ Acute liver disease or cirrhosis
- ☐ Diagnosis of inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- ☐ Has a definite or provisional diagnosis of <u>active</u> **nonradiographic axial spondyloarthritis** made by a VA/VA Community Care rheumatologist
- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist or locally-designated expert
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^2
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA)
- ☐ Completed hepatitis B screening (HBsAg, total antibody-to-hepatitis-B-core-antigen [anti-HBc] and antibody to hepatitis B surface antigen [anti-HBs]).^3
- ☐ Current or past completion of hepatitis C screening. Bimekizumab-bkzx may be initiated while waiting for test results.
- ☐ Documented results of pre-treatment liver enzymes, alkaline phosphatase, and bilirubin
- ☐ **Tumor necrosis factor inhibitor (TNFi)** is medically inadvisable, not tolerated or not adequate (i.e., NO or partial response after 3 months) or lost initial response.^4
- ☐ Had intolerance or inadequate response (i.e., NO or partial response after 3 months) to **ixekizumab** <u>and</u> **secukinumab**. Ixekizumab is the preferred interleukin-17A inhibitor in new starts.^4

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 patients of childbearing potential: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy
☐ For patients who are pregnant or plan to become pregnant: Counseling provided on potential risks vs benefits of treatment
☐ For patients who are lactating / providing breastmilk to an infant or planning to do so: Counseling provided on potential risks vs benefits of treatment.

Abbreviations: GI, gastrointestinal; ID, infectious diseases
See Targeted Immunomodulator Treatment Sequencing, footnote 4.

Other Justification

☐ _____

Footnotes

1 Antiviral prophylaxis for hepatitis B virus(HBV): Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used. In patients who are HBsAg-negative but anti-HBc-positive, the presence of antibody to hepatitis B surface antigen (antiHBs) 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

2 When possible, vaccinations should be updated before the patient initiates bimekizumab-bkzx. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with bimekizumab-bkzx, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected. The Centers for Disease Control (CDC) recommend that non-live and live vaccines should be administered 2 or more weeks before initiating interleukin immunosuppressives (see Altered Immunocompetence guidelines for vaccines and immunizations at: https://www.cdc.gov/vaccines/hcp/imz-best-practices/altered-immunocompetence.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html).

3 Anti-HBs may help to identify (1) patients who require initial or booster vaccination (anti-HBs titers ≥ 10 IU/L are generally considered protective) or (2) HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).

4 Applies only to new starts on bimekizumab-bkzx. Patients on bimekizumab-bkzx who are stable should not be switched to a criteria-required prior drug for nonmedical reasons.

5 **Targeted Immunomodulator Treatment Sequencing in Ankylosing Spondylitis** (1L = First-line; 2L = Second-line, etc.)
1L: TNFi
2L after a TNFi: IL-17Ai (ixekizumab preferred before secukinumab, which is preferred before bimekizumab-bkzx) or Janus kinase inhibitor (tofacitinib or upadacitinib)

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