Ustekinumab (STELARA) in Psoriatic Arthritis
Criteria for Use
February 2025

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 are selected, the patient will NOT meet criteria for ustekinumab.

- ☐ Untreated latent or active tuberculosis infection
- ☐ Uncontrolled, active, severe infection including evidence of *C. difficile* and undrained abscess (however, ustekinumab may be started / restarted once the infection is controlled)
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.[1] Ustekinumab may be initiated after starting antiviral prophylaxis.
- ☐ HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.[1] Ustekinumab may be initiated after starting antiviral prophylaxis.[2]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with ustekinumab.
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of ustekinumab
- ☐ History or development of reversible posterior leukoencephalopathy syndrome (RPLS)
- ☐ Known or suspected noninfectious pneumonia (e.g., interstitial pneumonia, eosinophilic pneumonia, cryptogenic pneumonia)
- ☐ Administration of Bacillus Calmette-Guerin (BCG) vaccine including therapeutic intravesical BCG within 1 year prior to starting ustekinumab (1 year after therapy).

Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist, dermatologist, or locally-designated expert expert.
- ☐ Has inflammatory articular disease (joint, spine, and/or entheseal) and a definite or provisional diagnosis of psoriatic arthritis**.** (Ustekinumab is ineffective for ankylosing spondylitis and is unlikely to be effective for axial PsA.)
- ☐ 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. (Ustekinumab may be initiated while waiting for test results.)
- ☐ ONE TNFI therapy is medically inadvisable, not tolerated, or not adequate (i.e., NO or partial response after 12 weeks or loss of initial response).
- ☐ ONE IL-17AI (ixekizumab preferred) is medically inadvisable (e.g., severe or recurrent Candida infections, etc.), not tolerated, or not adequate (i.e., NO or partial response after 12 weeks or loss of initial response).

Footnotes

[1] Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.

[2] Consult a hepatologist or infectious diseases expert for advice on whether to start antiviral prophylaxis to prevent HBV reactivation.

Supplemental Information

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

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]
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).
	ONE 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.
	ONE IL-17AI (ixekizumab preferred) is medically inadvisable (e.g., severe or recurrent Candida infections, etc.)	IL-17AI therapy may be medically inadvisable for reasons that include but are not limited to the presence of inflammatory bowel disease (IBD) and severe or recurrent Candida infections and, for brodalumab, suicide ideation or behavior (ixekizumab and secukinumab may be preferred over brodalumab).

Revised:

- February 2025 (Edited for Cerner / Oracle specs. Separated composite CFU into separate CFU for each indication.)
- 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.)
- June 2020 (updated infection and malignancy screening).
- March 2020 (extracted from Anti-Interleukin Biologics in Psoriasis and Psoriatic Arthritis Criteria for Use; Cerner reformatted; updated PsO and PsA; added CD and UC).
- December 2019 (Updated and streamlined).

Original: July 2019 (Anti-Interleukin Biologics in Psoriasis and Psoriatic Arthritis CFU).

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