

Secukinumab (COSENTYX) Subcutaneous Injection in Plaque Psoriasis Criteria for Use February 2024

VA 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 secukinumab for subcutaneous injection.

- Uncontrolled active infection, including undrained abscess (however, secukinumab 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 Secukinumab may be initiated after starting antiviral prophylaxis.¹
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with secukinumab.
- Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of secukinumab.²

Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- Chronic (≥ 6 months) moderate to severe plaque psoriasis (including involvement of nails only).
- Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated psoriasis expert.
- Secukinumab is prescribed at the FDA-approved dose for plaque psoriasis.
- Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- Completed hepatitis B screening (at minimum, HBsAg, total antibody-to-hepatitis-B-core-antigen (anti-HBc) and antibody to hepatitis B surface antigen [anti-HBs]).
- Current or past completion of hepatitis C screening. (Secukinumab may be initiated while waiting for test results.)
- Methotrexate monotherapy is medically inadvisable, not tolerated, or not adequate
- Phototherapy is medically inadvisable, inadequate, not available or not feasible.
- Tumor necrosis factor inhibitor (TNFi) is medically inadvisable, not tolerated or not adequate (i.e., NO or partial response after 3 months or loss of initial response).

Additional Inclusion Criteria

Select if appropriate.

- If HBsAg-negative but anti-HBc-positive: A gastroenterologist / hepatologist or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- For new starts: Had intolerance or inadequate response to ixekizumab. Ixekizumab is the preferred interleukin-17A inhibitor in new starts.
- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

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

Supplemental Information

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

Section	Criterion	Issues for Consideration
Inclusion Criteria	Methotrexate monotherapy is medically inadvisable....	Refer to <i>Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders</i> under Clinical Recommendations at the PBM SharePoint
	Methotrexate monotherapy is...not adequate	Inadequate methotrexate refers to NO treatment benefit after 3 months, of which at least 2 months is at the standard target dose, or inadequate partial response after 6 months. Target Doses: Methotrexate 15–25 mg ONCE WEEKLY orally, subcutaneously, or intramuscularly. Use lower doses if limited by toxicity.
	Phototherapy is medically inadvisable....	Reasons for phototherapy being medically inadvisable include (and are not limited to) <i>CONFIRMED (preferably by a written biopsy report)</i> history of skin cancer, melanoma or strong likelihood of developing them (e.g., Fitzpatrick skin type I or II = pale skin, easily sunburns).
	Tumor necrosis factor inhibitor (TNFi) is medically inadvisable, not tolerated or not adequate (i.e., NO or partial response after 3 months or loss of initial response).	TNFis 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.
	Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
	Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered. 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).
	Current or past completion of hepatitis C screening. (Secukinumab may be initiated while waiting for test results.).	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
Additional Inclusion Criteria	If HBsAg-negative but anti-HBc-positive: A gastroenterologist / hepatologist or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.	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. Management depends on the patient's risk of HBV reactivation. [Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. <i>Gastroenterology</i> . 2015;148(1):215–219. doi: https://doi.org/10.1053/j.gastro.2014.10.039 Ekpanyapong S, Reddy KR. Hepatitis B Virus Reactivation: What Is the Issue, and How Should It Be Managed? <i>Clin Liver Dis</i> . 2020 Aug;24(3):317-333. doi: 10.1016/j.cld.2020.04.002.]