Secukinumab (COSENTYX) 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 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:

- ☐ Has a definite or provisional diagnosis of active ankylosing spondylitis (or radiographic axial spondyloarthritis).
- ☐ Prescribed and monitored by a VA / VA Community Care rheumatologist or locally designated expert.
- ☐ Secukinumab is prescribed at the FDA-approved dose for ankylosing spondylitis.
- ☐ 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.)
- ☐ **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).^3

Additional Inclusion Criteria

Select if appropriate.

- ☐ If HBsAg-negative but anti-HBc-positive: A gastroenterologist / hepatologist or infectious diseases expert has been (e-)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.
3. Applies only to new starts on secukinumab. Patients on secukinumab who are stable should not be switched to a criteria-required prior drug for nonmedical reasons.

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