

Sarilumab (KEVZARA) in Polymyalgia Rheumatica Criteria for Use June 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 sarilumab.

- Uncontrolled, active, severe infection, including undrained abscess; however, sarilumab 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} Sarilumab may be initiated after starting antiviral prophylaxis.
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with sarilumab.
- Concomitant live or live-attenuated vaccines or administration of live or live-attenuated vaccines less than 2 weeks before initiation of sarilumab.
- Concomitant immunosuppressive biologic, immunosuppressive targeted synthetic drug (e.g., tofacitinib or other JAK inhibitors), cyclophosphamide, or alkylating agents.^{^3}
- Active hepatic disease or hepatic impairment.
- Baseline absolute neutrophil count (ANC) < 2000/mm³ unless associated with Duffy-null Associated Neutrophil Count.
- Baseline platelet count < 150,000/mm³
- Baseline alanine transaminase (ALT) and/or aspartate transaminase (AST) > 1.5x the upper limit of normal (ULN).

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- Diagnosis of polymyalgia rheumatica (PMR).
- Prescribed and monitored by a VA/VA Community Care rheumatologist or locally-designated expert.
- 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. Sarilumab may be initiated while waiting for test results.
- Initiated concurrently or after glucocorticoid therapy unless glucocorticoids are medically inadvisable.

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 infectious diseases expert has been (e-)consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy
- For patients who are lactating / providing breastmilk to infants: Counseling provided on the potential risks and benefits of treatment.

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.
- 2 When possible, vaccinations should be updated before the patient initiates sarilumab. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with sarilumab, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
- 3 Routine rescreening for hepatitis B or hepatitis C is not required for prescription renewals. Retesting in high-risk patients should be considered.

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