Tocilizumab (ACTEMRA) in Rheumatoid Arthritis

Criteria for Use

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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 tocilizumab.

- ☐ Uncontrolled active infection; however, tocilizumab may be started/restarted once treatment for the infection is initiated.
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.^1 Tocilizumab may be initiated after starting antiviral prophylaxis.
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with tocilizumab.
- ☐ Congenital or acquired immunodeficiency.
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of tocilizumab.^2
- ☐ 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/mm^3 unless associated with Duffy-null Associated Neutrophil Count
- ☐ Baseline platelet count <100,000/mm^3
- ☐ Baseline ALT and/or AST > 1.5x the upper limit of normal (ULN)

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- ☐ Diagnosis of moderate to severe rheumatoid arthritis.
- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist or locally-designated expert.
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.
- ☐ 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]).^4

☐ Current or past completion of hepatitis C screening. Tocilizumab may be initiated while waiting for test results.^4

☐ **Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated, or not adequate (i.e., NO response to ONE TNFI after 3 months, partial response to 3-month trials of TWO TNFIs = total 6 months), or lost response.

Additional Inclusion Criteria

Select if applicable.

☐ If HBsAg-negative but anti-HBc-positive and consult is deemed indicated: A GI/liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.

☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

☐ For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

Abbreviations: GI, gastrointestinal

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

3 Tocilizumab may be used in combination with methotrexate, other nonbiologic disease-modifying antirheumatic drugs (DMARDs), mycophenolate, hydroxychloroquine, or glucocorticoids. In general, concomitant use of potent immunosuppressives with tocilizumab should be avoided.

4 The safety of using tocilizumab in patients positive for HBV or HCV is unknown, as these patients were excluded from clinical trials. 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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