PAC NOTE: For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

INITIAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of the following criteria?
   • therapy initiated by or in consultation with a rheumatologist
   • previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   • 18 years of age or older
   • patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Actemra (tocilizumab) or another TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria
   • previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

   If yes, approve for 7 months by GPID for a maximum quantity limit of #4 syringes (3.6 mL) per 28 days.

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, do not approve.

   DENIAL TEXT: Our guideline for TOCILIZUMAB - SC requires a diagnosis of moderate to severe rheumatoid arthritis. Additional guideline requirements apply.

   For patients with moderate to severe rheumatoid arthritis, our guideline requires:
   • previous trial with at least one of the following DMARDs (disease-modifying antirheumatic drug) agents such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   • 18 years of age or older
   • patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Actemra (tocilizumab) or another TNF (tumor necrosis factor) inhibitor: Humira, Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria
   • previous trial with the preferred formulary TNF (tumor necrosis factor) inhibitors: Enbrel and Humira

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets the following criteria?
   - documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, approve for 12 months by GPID for a maximum quantity limit of #4 syringes (3.6 mL) per 28 days.
   If no, do not approve.

DENIAL TEXT: Our guideline for TOCILIZUMAB - SC renewal requires a diagnosis of moderate to severe rheumatoid arthritis. Additional guideline requirements apply.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:
   - documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy.

RATIONALE

Ensure appropriate utilization criteria are met for the management of requests for tocilizumab for use as monotherapy or in combination with methotrexate or other non-biologic DMARD and promote use of preferred agents Humira and Enbrel.

The recommended dosage of Actemra SQ for the treatment of RA is 162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response for patient weighing less than 100kg and 162mg administered subcutaneously every week for patients weighing 100kg or more.

When transitioning from Actemra intravenous therapy to subcutaneous administration administer the first subcutaneous dose instead of the next scheduled intravenous dose. Interruption of dose or reduction in frequency of administration of subcutaneous dose from every week to every other week dosing is recommended for management of certain dose-related laboratory changes including elevated liver enzymes, neutropenia, and thrombocytopenia.

FDA APPROVED INDICATION

Actemra (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

REFERENCE


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**TOCILIZUMAB - SQ**

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