

## Specialty Pharmacy Program

### Actemra® (tocilizumab)

#### DESCRIPTION

Actemra is an interleukin-6 receptor blocker indicated for the treatment of adult patients (18 years or older) with moderately to severely active rheumatoid arthritis.

#### APPROVAL DURATION AND QUANTITY LIMITS

##### Initial therapy

Approval duration: 12 weeks

Quantity limit: 1 dose (4 mg/kg) every 28 days

##### Maintenance therapy

Approval duration: lifetime

Quantity limit: 1 dose (4 mg/kg or 8 mg/kg\*) every 28 days

\* Must meet additional criteria for approval in section III below.

#### APPROVAL CRITERIA

- I. None of the following are present:
  - A. Tuberculosis (active or untreated) or any other serious infection.
  - B. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
  - C. Use of Actemra in combination with any other biologic medication.
  - D. Dose exceeds 800 mg.
- II. Moderately to severely active rheumatoid arthritis
  - A. Patient is 18 years of age or older AND
  - B. Patient has a diagnosis of moderately to severely active rheumatoid arthritis AND
  - C. Patient has had an inadequate response to at least one nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated, AND:
    1. Auranofin (Ridaura)
    2. Azathioprine (Imuran)
    3. Cyclophosphamide (Cytoxan or Neosar)
    4. Cyclosporine (Neoral or Sandimmune)
    5. Gold sodium thiomalate (Myochrysine)
    6. Hydroxychloroquine (Plaquenil)
    7. Leflunomide (Arava)
    8. Methotrexate
    9. Minocycline (Minocin or Dynacin)
    10. Penicillamine (Cuprimine, Depen)
    11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

D. Patient has had an inadequate response to at least two tumor necrosis factor (TNF) blocking agents (at least one being a self-administered product), or such therapy is contraindicated or not tolerated.

1. Self-administered products:

- a. Cimzia (certolizumab pegol)
- b. Enbrel (etanercept)
- c. Humira (adalimumab)
- d. Simponi (golimumab)

2. Administered by a healthcare professional:

- a. Remicade (infliximab)

III. The following criteria must be present for approval of a dose of 8 mg/kg:

A. Patient has had an inadequate response to a dose of 4 mg/kg after at least 12 weeks of treatment.