tocilizumab (Actemra®)

Commercial Pharmacy Benefit Drug Policy

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Interleukin-6 (IL-6) receptor antagonist

Drug Name	Quantity Limit
Actemra 162 MG/0.9ML SOLN PRSYR	1 syringe/week
Actemra ACTPen 162 MG/0.9ML SOLN A-INJ	1 pen injector/week

Condition(s) listed in policy *(see coverage criteria for details)*

- Giant cell arteritis (GCA)
- Polyarticular juvenile idiopathic arthritis (PJIA)
- Rheumatoid arthritis (RA)
- Systemic juvenile idiopathic arthritis (SJIA) / Still's disease)
- Systemic sclerosis associated interstitial lung disease (SSc-ILD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with Specialty Tier benefit MUST obtain specialty drugs through our contracted specialty pharmacies for medication to be covered.

The following condition(s) require Prior Authorization/Preservice:

<u>Giant cell arteritis (GCA)</u>

Initial Use:

1. Being used in combination with a tapering course of corticosteroids, AND
2. Not being used in combination with other targeted immunotherapies, AND
3. Dose does not exceed 162 mg given subcutaneously (SQ) once per week.

Reauthorization:

1. Patient is responding to Actemra or stable on therapy, AND
2. Not being used in combination with other targeted immunotherapies, AND
3. Dose does not exceed 162 mg given SQ once per week.

Coverage Period:
one year

Polyarticular juvenile idiopathic arthritis (PJIA)

Initial Use:

1. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), AND
2. Prescribed by or in consultation with a rheumatologist, AND
3. Inadequate response or intolerable side effect with one disease modifying anti-rheumatic drug (DMARD) or has a medical justification why methotrexate cannot be used, AND
4. Inadequate response, intolerable side effects, or contraindication to **Humira or Hadlima**, AND
5. Dose does not exceed FDA labeled maximum.

Reauthorization:

1. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), AND
2. Dose does not exceed FDA labeled maximum. AND
3. Patient is responding to therapy.

Covered Doses:

Weight	Maximum Dose
< 30kg	162 mg every three weeks
≥ 30kg	162 mg every two weeks

Coverage Period:
Initial: 16 weeks
Reauthorization: yearly based on continued response

Rheumatoid arthritis

1. Being prescribed by or in consultation with a Rheumatologist, AND
2. Inadequate response, intolerable side effect, or contraindication to methotrexate, AND
3. Not being used in combination with another targeted immunomodulator (i.e. anti-TNFs, IL-6 inhibitors, JAK inhibitors), AND
4. Dose does not exceed 162 mg given subcutaneously once per week, AND
5. Inadequate response, intolerable side effect, or contraindication to **Humira or Hadlima.**

Coverage Period:
one year

Systemic juvenile idiopathic arthritis (SJIA) / Still's disease

Initial Use:

1. Diagnosed or prescribed by a Rheumatologist, AND
2. Patient is 2 years of age or older, AND
3. Not being used in combination with other targeted immunotherapies, AND
4. Dose does not exceed FDA label maximum.

Reauthorization:

1. Patient is responding to Actemra, AND
2. Not being used in combination with other targeted immunotherapies, AND
3. Dose does not exceed FDA label maximum.

Covered Doses:

Weight	Maximum Dose
< 30kg	162 mg every three weeks
≥ 30kg	162 mg every two weeks

Coverage Period:
one year

Systemic sclerosis associated interstitial lung disease (SSc-ILD)

1. Recommended by a pulmonologist or rheumatologist, AND
2. Patient has systemic sclerosis, AND
3. Inadequate response, intolerable side effect to cyclophosphamide, mycophenolate, azathioprine, or systemic glucocorticoids or contraindication to all, AND
4. Dose does not exceed 162 mg given subcutaneously once per week.

Coverage Period:

one year

Additional Information

Disease Modifying Anti-Rheumatic Drugs (DMARDs):

- auranofin (Ridaura)
- azathioprine (Imuran)
- gold sodium thiomalate (Aurolate)
- hydroxychloroquine (Plaquenil)
- methotrexate (Rheumatrex)
- D-penicillamine (Cuprimine)
- sulfasalazine (Azulfidine)
- leflunomide (Arava)
- cyclosporine

References

1. Actemra prescribing information. Genentech Inc. 12/2022
2. Beukelman T, Patkar NM, Saag KG, et al 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis (JIA). Arthritis Care Res 2011; 63(5): 465-482.
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum 2013;65:2499-512.
4. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guidelines of the treatment of Rheumatoid Arthritis. Arthritis Care Res 2016;68:1-25.

Review History

Date of Last Annual Review: 4Q2023

Date of last revision: 01/03/2024
Changes from previous policy version:

- replace prerequisite therapy requirement for RA and pJIA to either Humira or Hadlima.

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee