

Actemra® (tocilizumab intravenous infusion)

When requesting Actemra® (tocilizumab intravenous infusion) for non-oncology indications, the individual requiring treatment must be diagnosed with an FDA-approved indication or an off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-Oncology Indications

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

Actemra is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Approved Non-Oncology Off-Label Compendial Use

Still's disease

Coverage Guidelines

Rheumatoid arthritis (RA)

For an initial authorization:

- Had a 3-month trial of at least one biologic agent OR
- Had a 3-month trial of at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine) AND
- Actemra IV is prescribed by or in consultation with a rheumatologist

Polyarticular juvenile idiopathic arthritis (pJIA)

For an initial authorization:

- Had tried at least one other agent including a biologic agent (e.g., etanercept, adalimumab, methotrexate) OR
- Actemra IV will be started concurrently with methotrexate, leflunomide, or sulfasalazine OR
- Has an absolute contraindication to methotrexate, leflunomide, or sulfasalazine (e.g., pregnancy, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias) OR
- Has aggressive disease AND
- Actemra IV is prescribed by or in consultation with a rheumatologist

Systemic juvenile idiopathic arthritis (sJIA)

For an initial authorization:

- Has tried one other systemic agent including a biologic agent (e.g., etanercept, methotrexate, corticosteroid) OR
- Had at least 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) AND
- Actemra IV is prescribed by or in consultation with a rheumatologist

Still's disease:

For an initial authorization

- Had a 2-month trial of or intolerance to at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate) AND
- Has tried one corticosteroid AND
- Actemra IV is prescribed by or in consultation with a rheumatologist

For re-authorization (for all indications):

- Has responded to Actemra therapy

Approval duration (initial):

- RA/sJIA/Stills disease: 3 months
- pJIA: 4 months

Approval duration (renewal): 12 months

Dosing Recommendations

Rheumatoid arthritis

The recommended starting dose is 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response.

Polyarticular juvenile idiopathic arthritis

For patients weighing less than 30 kg: the recommended dose is 10 mg/kg administered by intravenous every 4 weeks

For patients weighing 30 kg or more: the recommended dose is 8 mg/kg administered by intravenous every 4 weeks

Systemic juvenile idiopathic arthritis

For patients weighing less than 30 kg: the recommended dose is 12 mg/kg administered by intravenous every 2 weeks

For patients weighing 30 kg or more: the recommended dose is 8 mg/kg administered by intravenous every 2 weeks

References

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