

Actemra® (tocilizumab intravenous infusion and subcutaneous injection)

When requesting Actemra (tocilizumab intravenous infusion and subcutaneous injection) 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:

- Rheumatoid arthritis (RA)
- Polyarticular juvenile idiopathic arthritis (PJIA)
- Systemic juvenile idiopathic arthritis (SJIA)
- Giant cell arteritis (GCA)

Approved Non-oncology Off-label Compendial Uses

- Still's disease
- Polymyalgia rheumatica (PMR)
- Inflammatory arthritis associated with checkpoint inhibitor therapy
- Coronavirus disease 2019 (COVID-19)

Coverage Guidelines

Rheumatoid arthritis (RA)

The individual must meet **all** of the following criteria for initial authorization:

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

For reauthorization, the individual must show therapeutic response to Actemra (e.g., less joint pain, improved function, reduced dosage of corticosteroids).

Polyarticular juvenile idiopathic arthritis (pJIA)

The individual must meet the following criteria for initial authorization:

- Has tried at least one other agent for this condition (e.g., etanercept, adalimumab, methotrexate, sulfasalazine); OR
- Actemra 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 is prescribed by or in consultation with a rheumatologist.

For reauthorization, the individual must show therapeutic response to Actemra (e.g., less joint pain, improved function, reduced dosage of corticosteroids).

Systemic juvenile idiopathic arthritis (sJIA)

The individual must meet the following criteria for initial authorization:

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

For reauthorization, the individual must show therapeutic response to Actemra (e.g., less joint pain, improved function, reduced dosage of corticosteroids).

Giant cell arteritis (GCA)

The individual must meet **all** of the following criteria for initial authorization:

- Has tried one systemic corticosteroid (e.g., prednisone); AND
- Actemra is prescribed by or in consultation with a rheumatologist.

For reauthorization, the individual must show a response to Actemra (e.g., normalization of C-reactive protein [CRP] or erythrocyte sedimentation rate [ESR], reduction in signs or symptoms of GCA, reduced dosage of corticosteroids).

Still's disease

The individual must meet **all** of the following criteria for 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 is prescribed by or in consultation with a rheumatologist.

For reauthorization, the individual must show therapeutic response to Actemra (e.g., normalization of C-reactive protein, decrease in number of swollen joints, resolution of fever).

Polymyalgia rheumatica (PMR)

The individual must meet **all** of the following criteria for initial authorization:

- Has tried one systemic corticosteroid (e.g., prednisone); AND

- Actemra is prescribed by or in consultation with a rheumatologist.

For reauthorization, the individual must show a response to Actemra (e.g., normalization of C-reactive protein [CRP] or erythrocyte sedimentation rate [ESR], reduction in signs or symptoms of PMR, reduced dosage of corticosteroids).

Inflammatory arthritis associated with checkpoint inhibitor therapy

The individual must meet all of the following criteria for initial authorization:

- Is symptomatic despite a trial of at least ONE systemic corticosteroid (e.g., methylprednisolone, prednisone); AND
- Has tried at least ONE systemic nonsteroidal anti-inflammatory drug (NSAID); AND
- Actemra is prescribed by or in consultation with a rheumatologist or an oncologist.

For reauthorization, the individual must show therapeutic response to Actemra (e.g., less joint pain, improved function, reduced dosage of corticosteroids).

Coronavirus disease 2019 (COVID-19)

The individual must be diagnosed with cytokine release syndrome associated with COVID-19 for authorization.

Approval duration (initial):

- RA/sJIA/Still's disease/Inflammatory arthritis associated with checkpoint inhibitors: 3 months
- pJIA: 4 months
- PMR/GCA: 6 months
- COVID-19: 1 month

Approval duration (renewal): COVID-19 1 month, all other indications 12 months

Dosing Recommendations

Rheumatoid arthritis

Approve up to 8 mg/kg to a maximum of 800 mg per dose administered intravenously with an interval of at least 4 weeks between doses.

Subcutaneous adult dosage regimen

- For patients weighing less than 100 kg: Approve up to 162 mg per dose with an interval of at least 1 week between doses.
- For patients weighing 100 kg or more: Approve up to 162 mg per dose with an interval of at least 1 week between doses.

Polyarticular juvenile idiopathic arthritis

Intravenous dosage regimen

- For patients weighing less than 30 kg: Approve up to 10 mg/kg to a maximum of 800 mg per dose with an interval of at least 4 weeks between doses.
- For patients weighing 30 kg or more: Approve up to 8 mg/kg to a maximum of 800 mg per dose with an interval of at least 4 weeks between doses.

Subcutaneous dosage regimen

- For patients weighing less than 30 kg: Approve up to 162 mg per dose with an interval of at least 3 weeks between doses.
- For patients weighing 30 kg or more: Approve up to 162 mg per dose with an interval of at least 2 weeks between doses.

Systemic juvenile idiopathic arthritis

Intravenous dosage regimen

- For patients weighing less than 30 kg: Approve up to 12 mg/kg per dose with an interval of at least 2 weeks between doses.
- For patients weighing 30 kg or more: Approve up to 8 mg/kg per dose with an interval of at least 2 weeks between doses.

Subcutaneous dosage regimen

- For patients weighing less than 30 kg: Approve up to 162 mg per dose with an interval of at least 2 weeks between doses.
- For patients weighing 30 kg or more: Approve up to 162 mg per dose with an interval of at least 1 week between doses.

Giant cell arteritis

Approve up to 162 mg per dose administered subcutaneously with an interval of at least 1 week between doses.

Still's disease

Approve up to 8 mg/kg per dose administered intravenously with an interval of at least 2 weeks between doses.

Polymyalgia rheumatica

Approve up to 8 mg/kg per dose to a maximum of 800 mg per dose administered intravenously with an interval of at least 4 weeks between doses.

Inflammatory arthritis associated with checkpoint inhibitor therapy

Approve up to 8 mg/kg to a maximum of 800 mg per dose administered intravenously with an interval of at least 4 weeks between doses.

Coronavirus disease 2019

Approve up to a maximum of 800 mg per dose administered intravenously.

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