

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)
- Interstitial lung disease (ILD) associated with systemic sclerosis

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 hydroxychloroquine); AND
- Actemra is being prescribed by or in consultation with a rheumatologist.

For reauthorization, the individual must meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure (e.g., Clinical Disease Activity Index [CDAI], Patient Activity Scale [PAS]-II, Rapid Assessment of Patient Index Data 3 [RAPID-3]); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as decreased pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints.

- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

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, leflunomide, or nonsteroidal anti-inflammatory drug [NSAID]); OR
- Actemra will be started concurrently with methotrexate, leflunomide, or sulfasalazine; OR
- Has an absolute contraindication to methotrexate, leflunomide, or sulfasalazine (e.g., pregnancy, breast feeding, 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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., Physician Global Assessment [MD Global], Parent/Patient Global Assessment of Overall Well-being [PGA], C-reactive protein, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as less joint pain, decreased duration of morning stiffness, improved function or activities of daily living.

- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

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, anakinra, adalimumab, infliximab, canakinumab, methotrexate, leflunomide, sulfasalazine, 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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., C-reactive protein, erythrocyte sedimentation rate, resolution of fever, and/or reduced dosage of corticosteroids); OR

- Has experienced an improvement in at least one symptom compared to baseline such as less joint pain, decreased fatigue, and/or improved function or activities of daily living.
- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., C-reactive protein, erythrocyte sedimentation rate, resolution of fever, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as decreased headache or jaw pain, decreased fatigue, and/or improved vision.
- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

Interstitial lung disease (ILD) associated with systemic sclerosis

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

- Is 18 years of age or older; AND
- Patient has elevated acute phase reactants, defined as at least one of the following:
 - C-reactive protein (CRP) greater than or equal to 6 mg/mL; OR
 - Erythrocyte sedimentation rate (ESR) greater than or equal to 28 mm/h; OR
 - Platelet count greater than or equal to $330 \times 10^9/L$; AND
- Forced vital capacity (FVC) is greater than 55% of the predicted value; AND
- Diagnosis is confirmed by high-resolution computed tomography; AND
- Actemra is prescribed by or in consultation with a pulmonologist or a rheumatologist.

For reauthorization, the individual must meet the following criteria:

- Is 18 years of age or older; AND
- Actemra is prescribed by or in consultation with a pulmonologist or a rheumatologist; AND
- Has experienced a beneficial response to Actemra (e.g., a reduction in the anticipated decline in forced vital capacity, improvement in 6-minute walk distance, and/or reduction in number or severity of disease-related exacerbations).

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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., C-reactive protein, erythrocyte sedimentation rate, resolution of fever, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as less joint pain, decreased fatigue, and/or improved range of motion.
- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:
 - Has experienced an improvement in at least one objective measure compared to baseline (e.g., C-reactive protein, erythrocyte sedimentation rate, resolution of fever, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as less joint pain, decreased fatigue, and/or improved range of motion.
- Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

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 meet the following criteria:

- Has been established on Actemra therapy for at least 6 months; AND
- Meets one of the following:

- Has experienced an improvement in at least one objective measure compared to baseline (e.g., C-reactive protein, erythrocyte sedimentation rate, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline such as less joint pain, decreased fatigue, and/or improved function or activities of daily living.
- **Note:** A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.

Coronavirus disease 2019 (COVID-19)

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

Approval duration (initial):

- Still's disease/Inflammatory arthritis associated with checkpoint inhibitors/RA/sJIA/PMR/GCA/pJIA: 6 months
- ILD: 12 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 arthritisIntravenous dosage regimen

- For patients weighing less than 30 kg: Approve up to 12 mg/kg per dose with an interval of at least 1 week between doses.
- For patients weighing 30 kg or more: Approve up to 8 mg/kg per dose with an interval of at least 1 week 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 arteritisSubcutaneous dosage regimen

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

Intravenous dosage regimen

Approve up to 6 mg/kg to a maximum of 600 mg per dose administered intravenously with an interval of at least 4 weeks between doses.

Interstitial lung disease associated with systemic sclerosis 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 6 mg/kg per dose to a maximum of 600 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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