

Actemra® (tocilizumab)

When requesting Actemra® (tocilizumab) 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)
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Approved Non-oncology Off-label Compendial Uses

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

Coverage Guidelines

Rheumatoid arthritis (RA)

The individual must meet 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);
- Actemra is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by 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], Simplified Disease Activity Index [SDAI], etc.); OR

- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints)

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

The individual must meet the following criteria for initial authorization:

- Meets one of the following:
 - Has tried at least one other systemic therapy 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
- Actemra is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Physician Global Assessment [MD Global], Parent/Patient Global Assessment of Overall Well-being [PGA], Juvenile Arthritis Disease Activity Score [JDAS], serum markers [e.g., C-reactive protein], and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living).

Systemic Juvenile Idiopathic Arthritis (sJIA)

The individual must meet the following criteria for initial authorization:

- Meets one of the following:
 - 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);
- Actemra is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:

- Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate], improvement in rash or skin manifestations, resolution of fever, and/or reduced dosage of corticosteroids); OR
- Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain, tenderness, stiffness, swelling; decreased fatigue; and/or improved function or activities of daily living.)

Giant Cell Arteritis (GCA)

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

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

The individual must meet the following criteria for re-authorization:

- **Has been established on Actemra therapy for at least 6 months** (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (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 (e.g., decreased headache, decreased scalp or jaw pain, decreased fatigue, and/or improved vision).

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;
- 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 $330 \times 10^9/L$;
- Forced vital capacity (FVC) is greater than 55% of the predicted value;
- Diagnosis is confirmed by high-resolution computed tomography;
- Actemra is prescribed by or in consultation with a pulmonologist or a rheumatologist.

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

- Is 18 years of age or older;
- 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);
- Actemra is prescribed by or in consultation with a pulmonologist or a rheumatologist.

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);
- Has tried one corticosteroid;
- Actemra is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., C-reactive protein, erythrocyte sedimentation rate, improvement in rash or skin manifestations, resolution of fever, and/or reduced dosage of corticosteroids); OR
 - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain/tenderness, less stiffness, decreased fatigue, improved function or activities of daily living)

Polymyalgia Rheumatica (PMR)

The individual must meet the following criteria for initial authorization:

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

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (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 (e.g., decreased shoulder, neck, upper arm, hip, or thigh pain, improved range of motion, decreased fatigue, or decreased stiffness).

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);
- Has tried at least one systemic nonsteroidal anti-inflammatory drug (NSAID);
- Actemra is prescribed by or in consultation with a rheumatologist or an oncologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Actemra therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Actemra, is reviewed under initial authorization criteria.*);
- Meets one of the following:
 - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (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 (e.g., less joint pain/tenderness, less swelling, decreased fatigue, and/or improved function or activities of daily living).

Approval duration (initial): ILD 12 months; all others 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

Rheumatoid Arthritis

Intravenous dosage regimen

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.

Subcutaneous dosage regimen

- For patients weighing less than 100 kg: the recommended dose is 162 mg every other week, followed by an increase to every week based on clinical response.
- For patients weighing 100 kg or more: the recommended dose is 162 mg every week.

Polyarticular juvenile idiopathic arthritis

Intravenous dosage regimen

- For patients weighing less than 30 kg: the recommended dose is 10 mg/kg every 4 weeks.
- For patients weighing 30 kg or more: the recommended dose is 8 mg/kg every 4 weeks.

Subcutaneous dosage regimen

- For patients weighing less than 30 kg: the recommended dose is 162 mg once every 3 weeks.
- For patients weighing 30 kg or more: the recommended dose is 162 mg once every 2 weeks.

Systemic Juvenile Idiopathic Arthritis

Intravenous dosage regimen

- For patients weighing less than 30 kg: the recommended dose is 12 mg/kg every 2 weeks.

- For patients weighing 30 kg or more: the recommended dose is 8 mg/kg every 2 weeks.

Subcutaneous dosage regimen

- For patients weighing less than 30 kg: the recommended dose is 162 mg every 2 weeks.
- For patients weighing 30 kg or more: the recommended dose is 162 mg every week.

Giant Cell Arteritis

Subcutaneous dosage regimen

The recommended dose is 162 mg given once every week, in combination with a tapering course of glucocorticoids. Actemra can be used alone following discontinuation of glucocorticoids.

Intravenous dosage regimen

The recommended dose is 6 mg/kg every 4 weeks in combination with a tapering course of glucocorticoids. Actemra can be used alone following discontinuation of glucocorticoids.

Systemic Sclerosis-Associated Interstitial Lung Disease

The recommended dose is 162 mg administered as a subcutaneous injection once every week.

Still's disease

The recommended dose is up to 8 mg/kg per dose administered intravenously every 2 weeks.

Polymyalgia rheumatica

The recommended dose is up to 6 mg/kg to a maximum of 600 mg per dose administered intravenously every 4 weeks.

Inflammatory arthritis associated with checkpoint inhibitor therapy

The recommended dose is up to 8 mg/kg to a maximum of 800 mg per dose administered intravenously every 4 weeks.

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