

# Drug Policy

<b>Policy:</b>	201835	<b>Initial Effective Date: 02/18/2016</b>
<b>Code(s):</b>	HCPCS J3262, Q5135	<b>Annual Review Date: 10/17/2024</b>
<b>SUBJECT:</b>	<b>Actemra SC® (tocilizumab) Tyenne (tocilizumab-bavi)</b>	<b>Last Revised Date: 10/17/2024</b>

Subject to Site of Care

**Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.**

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please [click here](#).

## OVERVIEW

Actemra for subcutaneous (SC) injection and Tyenne are recombinant humanized interleukin-6 (IL-6) receptor inhibitor. IL-6 is a pro-inflammatory cytokine that is involved in various physiologic processes. Actemra SC has demonstrated efficacy and is indicated for the treatment of rheumatoid arthritis (RA) in adults with moderate to severe active RA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Actemra SC has been shown to inhibit and slow structural joint damage, improve physical function, and achieve a major clinical response in patients taking methotrexate (MTX). In addition to RA, Actemra SC is also indicated in adults with giant cell arteritis (GCA) and polyarticular juvenile idiopathic arthritis (PJIA). It is recommended to be given once weekly and may be given in combination with a tapering course of glucocorticoids. Actemra SC can be used alone following the discontinuation of glucocorticoids.

Actemra SC has Boxed Warnings regarding increased risk of developing serious infections which may lead to hospitalization or death. Patients who develop a serious infection should interrupt treatment with Actemra SC until infection is controlled. Patients should be monitored during and after treatment with Actemra SC, including tuberculosis (Tb).

## POLICY STATEMENT

This policy involves the use of Actemra SC and Tyenne. Prior authorization is recommended for medical benefit coverage of Actemra SC and Tyenne. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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# Drug Policy

Because of the specialized skills required for evaluation and diagnosis of patients treated with Actemra SC or Tyenne as well as the monitoring required for AEs and long-term efficacy, initial approval requires Actemra SC be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Actemra is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations under the medical benefit.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Actemra SC or Tyenne is recommended in those who meet one of the following criteria:

### Food and Drug Administration (FDA)-Approved Indications

1. Giant Cell Arteritis (GCA). Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) Initial Therapy. Approve if the patient meets the following criteria (i, ii, and iii):
    - i. The patient has tried one systemic corticosteroid (e.g., prednisone); AND
    - ii. This medication is prescribed by or in consultation with a rheumatologist; AND
    - iii. Site of care medical necessity is met\*
  - B) Patient is Currently Receiving tocilizumab (Subcutaneous or Intravenous). Approve if the patient meets BOTH of the following (i and ii):
    - i. Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii. Patient meets at least ONE of the following (a or b):
      - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product); OR  
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.
      - b) Compared with baseline (prior to initiating a tocilizumab product ), patient experienced an improvement in at least one symptom, such as decreased headache, scalp, or jaw pain; decreased fatigue, and/or improved vision.

### Dosing in GCA. Dosing must meet the following:

Subcutaneous:

162 mg once every week (in combination with a tapering course of glucocorticoids); based on clinical considerations, may consider 162 mg once every other week (with a tapering course of glucocorticoids). Tocilizumab may be administered as monotherapy following discontinuation of glucocorticoids.

### Initial Approval/ Extended Approval.

A) *Initial Approval: 6 months (180 days)*

# Drug Policy

**B) Extended Approval: 1 year (365 days)**

**2. Interstitial Lung Disease Associated with Systemic Sclerosis (SSc-ILD)** Approve only Actemra SC for 1 year if the patient meets ONE of the following (A or B):

**A) Initial Therapy.** Approve if the patient meets the following criteria (i, ii, iii, iv, v and vi):

- i.** The patient is 18 years of age or older; AND
- ii.** Patient has elevated acute phase reactants, defined as at least one of the following (a, b, or c):
  - a)** C-reactive protein (CRP)  $\geq$  6mg/mL; OR
  - b)** Erythrocyte sedimentation rate (ESR)  $\geq$  28 mm/h; OR
  - c)** The Platelet count  $\geq$  330 x 10<sup>9</sup>/L; AND
- iii.** The medication is prescribed by or in consultation with a rheumatologist or pulmonologist; AND
- iv.** Forced vital capacity (FVC) is > 55% of the predict value; AND
- v.** Diagnosis is confirmed by high-resolution computed tomography; AND
- vi.** Site of care medical necessity is met\*

**B) Patients Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product.** Approve if the patient meets the following criteria

- i.** The patient is 18 years of age or older; AND
- ii.** Patient has experienced a beneficial response to therapy over the previous 1 year while receiving a tocilizumab product; AND  
Note: For a patient who has received less than 1 year of therapy, response to therapy is from baseline prior to initiating a tocilizumab product. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, improvement in 6-minute walk distance, and/or reduction in the number or severity of disease-related exacerbations.
- iii.** The medication is prescribed by or in consultation with a rheumatologist or pulmonologist; AND
- iv.** Site of care medical necessity is met\*

**Dosing in SSc-ILD. Dosing must meet the following:**

Subcutaneous: 162 mg once every week

**Initial Approval/ Extended Approval.**

**A) Initial Approval: 1 year (365 days)**

**B) Extended Approval: 1 year (365 days)**

**3. Polyarticular Juvenile Idiopathic Arthritis (PJIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A) Initial Therapy.** Approve for if the patient meets the following criteria (i, ii, and iii):

- i.** The patient meets one of the following conditions (a, b, c, or d):
  - a)** Patient has tried one other systemic therapy for this condition; OR

# Drug Policy

Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of one biologic other than the requested drug also counts as a trial of one systemic therapy for Juvenile Idiopathic Arthritis. A biosimilar of Actemra does not count. Refer to Appendix for examples of biologics used for Juvenile Idiopathic Arthritis.

- b) The patient will be starting on Actemra SC concurrently with methotrexate (MTX), sulfasalazine, or leflunomide; OR
- c) The patient has an absolute contraindication to methotrexate (MTX) [e.g., pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias], sulfasalazine, or leflunomide; OR
- d) The patient has aggressive disease, as determined by the provider; AND
- ii. The medication is prescribed by or in consultation with a rheumatologist; AND
- iii. Site of care medical necessity is met\*

**B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product.** Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy)
- ii. Patient meets at least ONE of the following (a or b):
  - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product) ; OR  
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - b) Compared with baseline (prior to initiating Actemra), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

**Dosing in PJIA.** Dosing must meet the following:

Subcutaneous:

<30 kg: 162 mg once every 3 weeks

≥30 kg: 162 mg once every 2 weeks

Intravenous:

< 30kg: 10mg/kg

≥ 30kg: 8mg/kg

# Drug Policy

## **Initial Approval/ Extended Approval.**

A) *Initial Approval: 6 months (180 days)*

B) *Extended Approval: 1 year (365 days)*

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## **4. Rheumatoid Arthritis (RA).**

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

- i. Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND

Note: Examples of conventional DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial at least one biologic other than Actemra. A biosimilar of Actemra does not count. Refer to [Appendix](#) for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to “step back” and try a conventional synthetic DMARD.

- ii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

- ii. Patient meets at least ONE of the following (a or b):

- a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

- b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

**Dosing in RA.** Dosing must meet the following:

SubQ:

<100 kg: 162 mg once every other week; increase to 162 mg once every week based on clinical response

≥100 kg: 162 mg once every week

## **Initial Approval/ Extended Approval.**

A) *Initial Approval: 6 months (180 days)*

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# Drug Policy

**B) Extended Approval:** 1 year (365 days)

**5. Systemic Juvenile Idiopathic Arthritis (SJIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):

**i.** Patient has tried one other systemic therapy for this condition; AND

**Note:** Examples of other systemic therapies include a corticosteroid (oral, intravenous), a conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine], or a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of one biologic other than Actemra (e.g., Kineret [anakinra subcutaneous injection], a tumor necrosis factor inhibitor [e.g., an etanercept product, an adalimumab product, an infliximab product], or Ilaris [canakinumab subcutaneous injection]) also counts towards a trial of one other systemic therapy for systemic juvenile idiopathic arthritis. A biosimilar of Actemra does not count.

**ii.** The medication is prescribed by or in consultation with a rheumatologist.

**B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product.** Approve if the patient meets BOTH of the following (i and ii):

**i.** Patient has been established on therapy for at least 6 months; AND

**Note:** A patient who has received < 6 months of therapy or who is restarting therapy with this medication is reviewed under criterion A (Initial Therapy).

**ii.** Patient meets at least ONE of the following (a or b):

**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR

**Note:** Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

**Dosing for SJIA:** Dosing must meet the following:

Subcutaneous:

< 30 kg = 162 mg every two weeks

≥ 30 kg = 162 mg every week

**Initial Approval/ Extended Approval.**

**A) Initial Approval:** 6 months (180 days)

**B) Extended Approval:** 1 year (365 days)

**Other Uses with Supportive Evidence**

**6. Polymyalgia Rheumatica.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A) Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):



# Drug Policy

- i.** Patient has tried one systemic corticosteroid; AND  
Note: An example of a systemic corticosteroid is prednisone.
  - ii.** The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving a Tocilizumab Subcutaneous or Intravenous Product.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i.** Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
  - ii.** Patient meets at least ONE of the following (a or b):
    - a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating a tocilizumab product); OR  
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), resolution of fever, and/or reduced dosage of corticosteroids.
    - b)** Compared with baseline (prior to initiating a tocilizumab product), patient experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness; improved range of motion; and/or decreased fatigue.

# Drug Policy

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Actemra SC has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

**1. Concurrent use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Data are lacking evaluating concomitant use of Actemra SC another biologics or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples).<sup>1,11</sup> Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack of controlled trial data in support of additive efficacy.<sup>12</sup> Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate (MTX), leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Actemra SC.

**2. COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.  
Note: This includes requests for cytokine release syndrome associated with COVID-19.

**3. Crohn's Disease.** In a 12-week pilot study conducted in Japan, 36 adults with active Crohn's disease (Crohn's Disease Activity Index [CDAI]  $\geq$  150 and increased C-reactive protein [CRP]) were randomized, in a double-blind fashion to IV Actemra 8 mg/kg every 2 weeks; or alternating infusions of Actemra 8 mg/kg every 4 weeks and placebo (i.e., alternating with placebo every 2 weeks), or to placebo every 2 weeks.<sup>13</sup> At baseline the CDAI means ranged from 287 to 306. Patients had been treated with corticosteroids, mesalamine-type drugs, metronidazole, or elemental diet. Six patients in the placebo group, 4 on Actemra every 4 weeks and 1 on Actemra every 2 weeks dropped out. The mean reduction in the CDAI score in the Actemra 8 mg/kg every 2 week group was 88 points – from mean 306 to 218. Further studies are needed.

**4. Concurrent use with Otezla.** There is no evidence to suggest Otezla and Actemra provide superior outcomes to monotherapy.

**5.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.



# Drug Policy

## REFERENCES

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## FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3262, Q5135

## Appendix A

	Mechanism of Action	Examples of Inflammatory Indications*
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia®</b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA

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# Drug Policy

<b>Etanercept SC Products</b> (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
<b>Zymfentra®</b> (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
<b>Infliximab IV Products</b> (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Simponi®, Simponi® Aria™</b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
<b>Actemra®</b> (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
<b>Kevzara®</b> (sarilumab SC injection)	Inhibition of IL-6	RA, PMR
<b>Orencia®</b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret®</b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Stelara®</b> (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
<b>Siliq™</b> (brodalumab SC injection)	Inhibition of IL-17RA	PsO
<b>Bimzelx®</b> (bimekizumab-bkzx SC injection)	Inhibition of IL-17A and IL-17F	PsO
		SC formulation: AS, ERA, nr-axSpA, PsO, PsA
<b>Cosentyx®</b> (secukinumab SC injection, secukinumab IV infusion)	Inhibition of IL-17A	IV formulation: AS, nr-axSpA, PsA
		AS, nr-axSpA, PsO, PsA
<b>Taltz®</b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Ilumya™</b> (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
<b>Skyrizi®</b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO
		IV formulation: CD
<b>Tremfya™</b> (guselkumab SC injection)	Inhibition of IL-23	PsO
<b>Entyvio™</b> (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	SC formulation: UC
		IV formulation: CD, UC
<b>Oral Therapies/Targeted Synthetic DMARDs</b>		
<b>Otezla®</b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinco™</b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant®</b> (baricitinib tablets)	Inhibition of JAK pathways	RA
<b>Rinvoq®</b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
<b>Sotyktu™</b> (deucravacitinib tablets)	Inhibition of TYK2	PsO
<b>Xeljanz®</b> (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz® XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; PMR – Polymyalgia rheumatic; <sup>^</sup> Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.