Tocilizumab (Actemra®)	**Place of Service** **Office Administration** **Home Infusion Administration** **Infusion Center Administration** **Outpatient Facility Administration*** [***Prior authorization required – see section (1)] **HCPCS** (intravenous): **J3262** per 1mg **Self-Administration** *May be covered under the pharmacy benefit* **HCPCS** (subcutaneous): **J3590** NDC**:** 50242-0138-01 162mg/0.9ml

Conditions listed in policy (*see criteria for details*)

- Castleman's disease
- Cytokine release syndrome, CAR-T therapy induced
- Giant cell arteritis (GCA)
- Polyarticular juvenile idiopathic arthritis (PJIA)
- Rheumatoid arthritis, moderate to severe
- Systemic juvenile idiopathic arthritis (SJIA)/ Still's disease

AHFS therapeutic class: Interleukin-6 (IL-6) receptor antagonist, Antirheumatic

Mechanism of action: Tocilizumab is a humanized, monoclonal antibody that targets the IL-6 receptors. Tocilizumab binds to soluble and membrane-bound IL-6 receptors and inhibits IL-6 signaling.

(1) Special Instructions and Pertinent Information

Subcutaneous(SC) Actemra is managed under the Outpatient Pharmacy Benefit. If the patient has a pharmacy benefit, please contact Blue Shield Pharmacy Services to obtain a prior authorization. To submit a request to the medical benefit, please submit clinical information for prior authorization review via fax, including medical rationale why the patient cannot self-administer in the home.

Intravenous(IV) Actemra is managed under the Medical Benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF INTRAVENOUS ACTEMRA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving their first infusion of Actemra or is being re-initiated on Actemra after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*
   Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Actemra based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Actemra based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Actemra® (tocilizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Castleman's disease

- One of the following:
  - Diagnosis of Multicentric Castleman's disease, and relapsed, refractory, or progressive disease
    OR
  - Diagnosis of Unicentric Castleman's disease, **AND** all of the following:
    - Relapsed, refractory, or progressive disease, and
    - Patient is HIV and HHV-8 negative, and
    - Disease is surgically unresectable, and
    - History of an inadequate response, intolerance, or contraindication to Rituxan

AND

- Not used with another targeted immunomodulator

Covered Doses
Up to 8 mg/kg intravenous infusion every 4 weeks

Coverage Period
Yearly based on continued response to therapy.

ICD-10:
D36.0, R59.0, R59.1, R59.9

Cytokine release syndrome, Chimeric Antigen Receptor therapy (CAR-T) induced

- On Chimeric Antigen Receptor therapy (CAR-T), **AND**
- Not used with another targeted immunomodulator

Covered Doses

Patient Wt	Maximum Dose
< 30 kg	12 mg/kg intravenous infusion as often as every 8 hrs for up to 4 doses, not to exceed 800 mg/dose
≥ 30 kg	8 mg/kg intravenous infusion as often as every 8 hrs for up to 4 doses, not to exceed 800 mg/dose

Coverage Period
One CAR-T treatment course

No reauthorization

ICD-10: L78.8, I78.9

Giant cell arteritis (GCA)

- Diagnosis of giant cell arteritis, **AND**
- Patient is currently taking steroids, **AND**
- Not used with another targeted immunomodulator

Covered Doses

Subcutaneous(SC) Actemra is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact Blue Shield Pharmacy services to obtain a prior authorization.

Subcutaneous self-administration: Up to 162 mg subcutaneous injection every week

Coverage Period

Yearly based on continued response to therapy

ICD-10:

M31.6

Polyarticular juvenile idiopathic arthritis (PJIA)

- Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), **AND**
- Diagnosed by a Rheumatologist (the prescribing physician does not have to be a Rheumatologist), **AND**
- Patient is 2 years of age or older, **AND**
- Inadequate response, intolerance, or contraindication to one DMARD agent (see list above), or medical justification why methotrexate cannot be used, **AND**
- Inadequate response or intolerable side effect to Enbrel and Humira, **AND**
- Not used with another targeted immunomodulator

Covered Doses

Intravenous:

Weight	Maximum Dose and Frequency
< 30 kg	10 mg/kg every 4 weeks
≥ 30 kg	8 mg/kg every 4 weeks

Subcutaneous(SC) Actemra is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact Blue Shield Pharmacy services to obtain a prior authorization.

Subcutaneous:

Weight	Maximum Dose and Frequency
< 30 kg	162 mg every three weeks
> 30 kg	162 mg every two weeks

Coverage Period

Cover up to 16 weeks.

Reauthorization: Yearly based on continued response

ICD-10:

M08.20-M08.272

Rheumatoid arthritis, moderate to severe

- Diagnosed or recommended by a rheumatologist, **AND**
- Patient is ≥18 years of age, **AND**
- Not being used in combination with other targeted therapies (e.g., immunomodulators) for rheumatoid arthritis, **AND**
- Medical rationale why two of the following, Enbrel, Humira, infliximab (Inflectra or Remicade), and Xeljanz/Xeljanz XR, cannot be used with any conventional DMARDs

Covered Doses

Intravenous infusion:

Up to 8 mg/kg every 4 weeks. Actemra doses exceeding 800 mg per infusion are not recommended in RA patients.

Subcutaneous(SC) Actemra is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact Blue Shield Pharmacy services to obtain a prior authorization.

Subcutaneous self-administration:

Up to 162 mg SC weekly

Coverage Period
Cover up to 24 weeks.

Reauthorization: Yearly based on continued response

ICD-10: (X=0-9)
M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

Systemic juvenile idiopathic arthritis (SJIA)/ Still's disease

- Diagnosis of systemic juvenile idiopathic arthritis (SJIA)/Still's disease, **AND**
- Diagnosed by a Rheumatologist (the prescribing physician does not have to be Rheumatologist), **AND**
- Patient is 2 years of age or older, **AND**
- Not used with another targeted immunomodulator

Covered Doses
Intravenous

Weight	Maximum Dose and frequency
< 30 kg	12 mg/kg IV every 2 weeks
≥ 30 kg	8 mg/kg IV every 2 weeks

Subcutaneous(SC) Actemra is managed under the Outpatient Pharmacy Benefit unless medical rationale is provided why the patient cannot self-administer this medication in the home. Please contact Blue Shield Pharmacy services to obtain a prior authorization.

Subcutaneous

Weight	Maximum Dose and frequency
< 30 kg	162 mg SC every 2 weeks
≥ 30 kg	162 mg SC every weeks

Coverage Period
Cover up to 12 weeks

Reauthorization: Yearly based on continued response

ICD-10: M08.20-M08.272

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Actemra® (tocilizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use with other targeted immunomodulators

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

• 80 mg, 200 mg, 400 mg (single-use vials)
• 162 mg (syringes)

Examples of Conventional DMARDs

Auranofin (Ridaura®)
Azathioprine (Imuran®)
Cyclosporine (Neoral®)
Hydroxychloroquine (Plaquenil®)
Methotrexate (Rheumatrex®)
D-Penicillamine (Cuprimine®)
Sulfasalazine (Azulfidine®)
Leflunomide (Arava®)

(6) References

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- Actemra®. National Comprehensive Cancer Network (NCCN) Drugs & Biologics compendium. 2019. Available by subscription at www.nccn.org.
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(7) Policy Update

Date of last revision: 4Q2019

Date of next review: 2Q2020

Changes from previous policy version:

- Section (2): Rheumatoid arthritis – Expanded selection of preferred biologics to Inflectra, and Xeljanz/Xeljanz XR
  Rationale: Selection of preferred agents is supported by similar safety and efficacy and are guideline supported agents.