

tocilizumab intravenous

Commercial Medical Benefit Drug Policy

(tocilizumab) Actemra IV
(tocilizumab-bavi) Tofidence IV
(tocilizumab-aazg) Tyenne IV

Place of Service

Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

Mechanism of Action: Interleukin-6 (IL-6) receptor antagonist

HCPCS:

J3262:Injection, tocilizumab, 1 mg
Q0249:Injection, tocilizumab, for hospitalized adults and pediatric patients (2 years of age and older) with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg
Q5133:Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135:Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg

How Supplied:

Actemra / Tofidence / Tyenne (intravenous): 80 mg/4 mL, 200 mg/10 mL, and 400 mg/20 mL (single-dose vials)

Condition(s) listed in policy *(see coverage criteria for details)*

- Castleman's Disease
- COVID-19 treatment
- Cytokine Release Syndrome (CRS)
- Giant Cell Arteritis (GCA)
- Graft Versus Host Disease (GVHD)
- Immune Checkpoint Inhibitor Related Toxicities
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- Rheumatoid Arthritis (RA)
- Systemic Juvenile Idiopathic Arthritis (sJIA) and Still's disease

The following conditions do not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and are not covered:

- Combination use with other targeted immunomodulators

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Tocilizumab, given by subcutaneous (SC) injection: Refer to the "Self-Administered Drugs" medical benefit drug policy for commercial plans.

Tocilizumab, given by intravenous (IV) injection is managed under the Medical Benefit.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

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

1. Patient is receiving their first dose of tocilizumab or is being re-initiated on tocilizumab 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 tocilizumab based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on tocilizumab 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.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Castleman's Disease

Meets medical necessity if all the following are met:

1. Meets ONE of the following:

- a. Diagnosis of relapsed, refractory, or progressive Multicentric Castleman's disease
- b. Diagnosis of Unicentric Castleman's disease, AND all of the following:
 - i. Relapsed, refractory, or progressive disease
 - ii. Patient is HIV and HHV-8 negative
 - iii. Disease is surgically unresectable
 - iv. History of an inadequate response, intolerance, or contraindication to rituximab
2. Not being used in combination with other targeted immunomodulators
3. For Actemra or Tofidence request: Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Covered Doses:

Up to 8 mg/kg given intravenously every 2 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

D36.0, R59.0, R59.1, R59.9

COVID-19 treatment

Meets medical necessity if all the following are met:

1. Patient is hospitalized with COVID-19
2. Age is consistent with the FDA-approved indication (2 years and older)
3. Patient is receiving systemic corticosteroids
4. Patient requires supplemental oxygen with one of the following:
 - a. Non-invasive mechanical ventilation
 - b. Extracorporeal membrane oxygen (ECMO)

Covered Doses:

Patients less than 30 kg weight: Up to 12 mg per kg given intravenously for up to 2 doses

Patients at or above 30 kg weight: Up to 8 mg per kg given intravenously for up to 2 doses

Coverage Period:

Per hospitalization

ICD-10:

U07.1

Cytokine Release Syndrome (CRS)

Meets medical necessity if all the following are met:

1. Meets ONE of the following:
 - a. Related to chimeric antigen receptor therapy (CAR-T)
 - b. Related to Blincyto (blinatumomab)
 - c. Related to Tecvayli (teclistamab-cqyv)
2. Not being used in combination with other targeted immunomodulators
3. For Actemra or Tofidence request: Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Covered Doses:

tocilizumab intravenous

Weight	Maximum Dose
< 30 kg	Up to 2 mg/kg given intravenously as often as every 8 hrs for up to 4 doses, not to exceed 800 mg/dose
≥ 30 kg	Up to 8 mg/kg given intravenously as often as every 8 hrs for up to 4 doses, not to exceed 800 mg/dose

Coverage Period:

A course of 4 doses

No reauthorization

ICD-10:

I78.8, I78.9

Giant Cell Arteritis (GCA)

Meets medical necessity if all the following are met:

Initial:

1. Patient is currently taking steroids
2. Not used with another targeted immunomodulator
3. For Actemra or Tofidence request, one of the following (a or b):
 - a. Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product
 - b. Inadequate response, intolerable side effect, or contraindication to preferred product (e.g. Rinvoq)

Reauthorization:

1. Patient has continued response to therapy
2. Not being used with another targeted immunomodulator

Covered Doses:

Up to 6 mg/kg given intravenously every 4 weeks. Doses exceeding 600 mg per infusion are not recommended in GCA patients

Coverage Period:

Yearly

ICD-10:

M31.6

Graft Versus Host Disease (GVHD)

Meets medical necessity if all the following are met:

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)
2. For Actemra or Tofidence request: Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Covered Doses:

Up to 8 mg/kg given intravenously every 2 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

D89.810, D89.812, D89.813, T86.09

Immune Checkpoint Inhibitor Related Toxicities**Meets medical necessity if all the following are met:**

1. Meets ONE of the following:
 - a. Being used as additional corticosteroid-sparing immunosuppression to manage hepatobiliary adverse event related to immune checkpoint inhibitor therapy (e.g. Grade 2-4 elevated ALT/AST, alkaline phosphatase)
 - b. Being used to treat corticosteroid-refractory hemophagocytic lymphohistiocytosis (HLH)-like syndrome related to immune checkpoint inhibitor therapy
 - c. Corticosteroid-refractory pneumonitis related to immune checkpoint inhibitor therapy
 - d. Patient has severe inflammatory arthritis due to immune checkpoint inhibitor, and ALL of the following:
 - i. Prescribed by or in consultation with Rheumatologist
 - ii. Inadequate response, intolerable side effect or contraindication to corticosteroids
2. Not being used in combination with other targeted immunomodulators
3. For Actemra or Tofidence request: Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Covered Doses:

Up to 8 mg/kg given intravenously once weekly

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

M06.4, M31.5, M31.6, M35.3

Polyarticular Juvenile Idiopathic Arthritis (pJIA)**Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response or intolerable side effect to one DMARD agent, or medical justification why methotrexate cannot be used
3. Not being used in combination with other targeted immunomodulators
4. For Tyenne request: Inadequate response or intolerable side effect with TWO BSC-preferred agents (e.g., adalimumab-aacf 40 mg, Simlandi 20 mg, Enbrel, Rinvoq/Rinvoq LQ, Xeljanz/Xeljanz XR) or contraindication to all listed agents
5. For Actemra or Tofidence request, meets ALL the following:
 - a. Inadequate response or intolerable side effect with ONE BSC-preferred agent (e.g., adalimumab-aacf 40 mg, Simlandi 20 mg, Enbrel, Rinvoq/Rinvoq LQ, Xeljanz/Xeljanz XR) or contraindication to all listed agents
 - b. Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Reauthorization

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators

Covered Doses:

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

Coverage Period:

Yearly

ICD-10:

M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272

Rheumatoid Arthritis (RA)

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to methotrexate
3. Not being used in combination with other targeted immunomodulators
4. For Tyenne request: Inadequate response, intolerable side effect with BSC-preferred agent infliximab (Avsola and Inflectra) or contraindication to infliximab products
5. For Actemra or Tofidence request, meets ALL the following:
 - a. Inadequate response, intolerable side effect with BSC-preferred agent infliximab (Avsola and Inflectra) or contraindication to infliximab products
 - b. Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Reauthorization

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators

Covered Doses:

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

Coverage Period:

Yearly

ICD-10:

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

Systemic Juvenile Idiopathic Arthritis (sJIA) and Still's disease

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a rheumatologist
2. Patient is 2 years of age or older
3. Not being used in combination with other targeted immunomodulators
4. For Actemra or Tofidence request: Intolerable side effect or contraindication with Tyenne (tocilizumab-aazg) that is not expected with the requested tocilizumab product

Reauthorization

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators

Covered Doses:

Weight	Maximum Dose and Frequency
< 30 kg	Up to 12 mg/kg given intravenously every 2 weeks
≥ 30 kg	Up to 8 mg/kg given intravenously every 2 weeks

Coverage Period:

Initial: 12 weeks

Reauthorization: Yearly

ICD-10:

M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272

Additional Information

Disease Modifying Anti-Rheumatic Drugs (DMARDs):

- auranofin (Ridaura)
- azathioprine (Imuran)
- cyclosporine
- gold sodium thiomalate (Aurolate)
- hydroxychloroquine (Plaquenil)
- methotrexate (Rheumatrex)
- D-penicillamine (Cuprimine)
- sulfasalazine (Azulfidine)
- leflunomide (Arava)
- cyclosporine

References

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5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guidelines of the treatment of Rheumatoid Arthritis. *Arthritis Care Res* 2021; 73(7):924-939.
6. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
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8. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2025). Available by subscription at www.nccn.org.
9. National Comprehensive Cancer Network. Hematopoietic cell transplantation (Version 3.2025). Available by subscription at www.nccn.org.
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11. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 2.2025). Available by subscription at www.nccn.org.
12. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the treatment of juvenile idiopathic arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. *Arthritis Rheum* 2021;74(4):521-537.
13. Tofidence (tocilizumab-bavi). Prescribing Information. Biogen MA Inc.; Cambridge, MA. December 2024.
14. Tyenne (tocilizumab-aazg). Prescribing Information. Fresenius Kabi USA LLC; Lake Zurich, IL. February 2025.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- COVID-19 treatment: Expand coverage to include pediatric patients 2 years of age and older (Rationale: FDA expansion 8/2025)

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*