blue california
Promise Health Plan

tocilizumab intravenous

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
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
- 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.

Tocilizumab, given subcutaneously, is managed under the Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

Tocilizumab, given intravenously, is managed under the Medical Benefit.

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 request: intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) that is not expected with the requested tocilizumab product

Covered Doses:
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

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. For Actemra request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) that is not expected with the requested tocilizumab product

Covered Doses:

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 reauthorizaton

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 request, one of the following (a or b):
   a. Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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 request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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 request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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. Inadequate response, intolerable side effect, or contraindication with two of the following agents (e.g., adalimumab, Enbrel, Xeljanz/Xeljanz XR) or contraindication to all listed agents
4. Not being used in combination with other targeted immunomodulators
5. For Actemra request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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:
1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to methotrexate
3. Meets EITHER of the following:
   a. Inadequate response, intolerable side effect with two treatments (e.g., adalimumab+DMARD, Enbrel+DMARD, infliximab (Avsola, Inflectra, Renflexis)+DMARD, Rinvoq, and Xeljanz/XeljanzXR) or contraindication to all listed treatments
   b. Meets EITHER of the following:
      i. Patient has had an inadequate response or intolerable side effect with Avsola, Inflectra, or Renflexis with any conventional DMARD
      ii. Patient has had no treatment with infliximab and has contraindication to all infliximab products (Avsola, Inflectra, Renflexis)
4. Not used with another targeted immunomodulator

5. For Actemra request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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:
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 request: Intolerable side effect or contraindication with tocilizumab (i.e., Tofidence and Tyenne) 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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3. American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
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6. MCG Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
7. National Comprehensive Cancer Network. Castleman Disease (Version 2.2025). Available by subscription at www.nccn.org.
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.
10. National Comprehensive Cancer Network. Management of immunotherapy-related toxicities (Version 1.2025). Available by subscription at www.nccn.org.
11. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 2.2025). Available by subscription at www.nccn.org.
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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:

- No clinical change following annual review.

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