tocilizumab, IV (Actemra®) **tocilizumab-bavi, IV (Tofidence™)**	**Place of Service** **Office Administration** **Home Infusion Administration** **Infusion Center Administration** **Outpatient Facility Administration** **HCPCS** Actemra: **J3262** per 1 mg Tofidence: **Q5133** per 1 mg

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

- Castleman's disease
- Cytokine release syndrome, CAR-T therapy induced
- Giant cell arteritis
- Graft versus host disease
- Polyarticular juvenile idiopathic arthritis
- Rheumatoid arthritis
- Systemic juvenile idiopathic arthritis/ 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

Tocilizumab, given by intravenous (IV) injection, is managed under the Medical Benefit. Please submit clinical information for prior authorization review.

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

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

Castleman's disease

1. One of the following:
    a. Diagnosis of Multicentric Castleman's disease, and relapsed, refractory, or progressive disease,

       OR

    b. Diagnosis of Unicentric Castleman's disease, AND all of the following:
        i. Relapsed, refractory, or progressive disease, and
        ii. Patient is HIV and HHV-8 negative, and
        iii. Disease is surgically unresectable, and
        iv. One of the following:
            1. History of an inadequate response or intolerance to a rituximab products, or
            2. Has not been treated with rituximab and has a contraindication to all rituximab products

AND

2. Not used with another targeted immunomodulator

Covered Doses
Up to 8 mg/kg intravenous infusion 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, chimeric antigen receptor therapy (CAR-T) induced

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

Covered Doses

Weight	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)

1. Patient is currently taking steroids, **AND**
2. Not used with another targeted immunomodulator

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

Coverage Period
Yearly based on continued response to therapy

ICD-10:
M31.6

Graft versus host disease

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)

Covered Doses
Up to 8 mg/kg intravenous infusion every 2 weeks

Coverage Period
Indefinite

ICD-10:
D89.810, D89.12, D89.813, T86.09

Polyarticular juvenile idiopathic arthritis (PJIA)

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response, intolerance, or contraindication to one DMARD agent, or medical justification why methotrexate cannot be used, **AND**
3. Inadequate response, intolerable side effect or contraindication with at least two of the following: anti-TNFs, JAK inhibitor, **AND**
4. Not used with another targeted immunomodulator

Covered Doses

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

Coverage Period
Cover up to 16 weeks

Reauthorization: Yearly based on continued response

ICD-10:
M08.20-M08.272

Rheumatoid arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response, intolerable side effect, or contraindication to methotrexate, **AND**
3. Not used in combination with another targeted immunomodulator (e.g., TNF inhibitors, IL-6 inhibitors, JAK inhibitors), **AND**
4. Either of the following:
    a. Inadequate response, intolerable side effect or contraindication with at least two of the following: anti-TNFs+DMARDs, JAK inhibitors, IL-6 inhibitor, or abatacept,

    OR

    b. Either of the following:
        i. Patient has had an inadequate response or intolerable side effect with Avsola, Inflectra, or Renflexis with any conventional DMARD, or

ii. Patient has had no treatment with infliximab and has contraindication to all infliximab products, Avsola, Inflectra, Renflexis

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

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

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Patient is 2 years of age or older, **AND**
3. Not used with another targeted immunomodulator

Covered Doses

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

Intravenous: 80 mg/4 mL, 200 mg/10 mL, and 400 mg/20 mL (single-dose vials)

Subcutaneous: 162 mg (single-dose prefilled syringe)

Examples of Conventional DMARDs

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

(6) References

- Actemra® (tocilizumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; 6/2022.
- AHFS®. Available by subscription at http://www.lexi.com
- American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
- Beukelman T, Patkar NM, Saag KG, et al 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis (JIA). Arthritis Care Res 2011; 63(5): 465-482.
- DeBandt M. Lessons for lupus from tumour necrosis factor blockade. Lupus 2006; 15(11):762.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Lateef A, Petria M. Biologics in the treatment of systemic lupus erythematosus. Curr Opin Rheumatol. 2010;22(5):504-509.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- National Comprehensive Cancer Network. B-cell lymphomas (Version 4.2022). Available by subscription at www.nccn.org.
- National Comprehensive Cancer Network. Hematopoietic cell transplantation (Version 1.2022). Available by subscription at www.nccn.org.
- National Comprehensive Cancer Network. Management of immunotherapy-related toxicities (Version 1.2022). Available by subscription at www.nccn.org.
- Ramos-Casals M et al. Autoimmune diseases induced by TNF-targeted therapies: analysis of 233 cases Medicine (Baltimore). 2007;86(4):242.
- Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum 2013;65:2499-512.
- Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res 2012; 64(5): 625-639.
- Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guidelines of the treatment of Rheumatoid Arthritis. Arthritis Care Res 2016;68:1-25.
- Tofidence™ (tocilizumab-bavi) [Prescribing Information]. Cambridge, MA: Biogen MA Inc.; 9/2023.

(7) Policy Update

Date of last revision: 2Q2024
Date of next review: 4Q2024
Changes from previous policy version:

- Added Q5133 tocilizumab-bavi (tofidence), biosimilar, 1 mg, effective 4/1/2024

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee