

Medical Policy Manual **Approved Rev: Do Not Implement until 9/30/26**

Tocilizumab (Actemra®); Tocilizumab-anoh (Avtozma®); Tocilizumab-bavi (Tofidence™); Tocilizumab-aazg (Tyenne®), tocilizumab-aazg, tocilizumab-anoh

Some agents on this policy may require step therapy See “Step Therapy Requirements for Provider Administered Specialty Medications” Document at:

https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs)
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA)
- Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA)
- Adult patients with giant cell arteritis (GCA)
- Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function
- Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
- Hospitalized adult **and pediatric** patients **aged 2 years and older** with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

Compendial Uses

- Unicentric Castleman disease
- Multicentric Castleman disease
- Oligoarticular juvenile idiopathic arthritis
- Immune checkpoint inhibitor-related toxicity
- Acute graft versus host disease
- Cytokine release syndrome (other than severe or life-threatening CAR T cell-induced CRS)
- Polymyalgia rheumatica
- Moderate to severe rheumatoid arthritis with no previous treatment failure
- **Kaposi-sarcoma herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS)**

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving treatment for COVID-19 will be managed according to the member's inpatient benefit.



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All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Articular juvenile idiopathic arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic juvenile idiopathic arthritis (sJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Immune checkpoint inhibitor-related toxicity, and acute graft versus host disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Initial requests

Result of a chest high-resolution computed tomography (HRCT) study.

Polymyalgia rheumatica and immune checkpoint inhibitor-related inflammatory arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

PRESCRIBER SPECIALTIES



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This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, and polymyalgia rheumatica: rheumatologist
- Systemic sclerosis-associated interstitial lung disease: rheumatologist or pulmonologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Cytokine release syndrome, unicentric Castleman disease, multicentric Castleman disease, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity, **Kaposi-sarcoma herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome**: oncologist or hematologist

COVERAGE CRITERIA

Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when either of the following criteria is met:

- Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
- Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Articular juvenile idiopathic arthritis

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease



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Systemic juvenile idiopathic arthritis (sJIA)

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Giant cell arteritis (GCA)

Authorization of 12 months may be granted for adult members for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- Temporal artery biopsy or cross-sectional imaging
- Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP]).

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Authorization of 12 months may be granted for adult members for treatment of sclerosis-associated interstitial lung disease when the diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Cytokine release syndrome

Authorization of 1 month may be granted for the prophylaxis or treatment of cytokine release syndrome (CRS).

Unicentric Castleman disease

Authorization of 12 months may be granted for treatment of unicentric Castleman disease when all of the following criteria are met:

- The member is human immunodeficiency virus (HIV)-negative.
- The member is human herpesvirus-8-negative.
- The requested medication will be used as a single agent.
- The disease has progressed following treatment of relapsed/refractory disease or has surgically unresectable disease.

Multicentric Castleman disease

Authorization of 12 months may be granted for treatment of multicentric Castleman disease when **any** of the following criteria is met:

- The member meets both of the following:
 - The requested medication will be used as a single agent.
 - The disease has progressed following treatment of relapsed/refractory or progressive disease.
- **The member meets either of the following:**
 - **The member has active disease with no organ failure that is human immunodeficiency virus (HIV)-negative and human herpesvirus-8-negative.**
 - **Fulminant/severe disease that is human herpesvirus-8-negative.**
- The requested medication is being used as a substitute for siltuximab when there is a shortage of siltuximab or it is not available.

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Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Acute graft versus host disease

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for treatment of polymyalgia rheumatica (PMR) when any of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has had a disease flare during a taper with systemic corticosteroids.
- Member has had an inadequate response to methotrexate.
- Member has had an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

Kaposi-sarcoma herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS)

Authorization of 12 months may be granted for treatment of KSHV-Associated Inflammatory Cytokine Syndrome (KICS) when the member has refractory or progressive disease.

CONTINUATION OF THERAPY

Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Articular juvenile idiopathic arthritis



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Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Systemic juvenile idiopathic arthritis (sJIA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for sJIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Giant cell arteritis (GCA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for GCA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Headaches
- Scalp tenderness
- Tenderness and/or thickening of superficial temporal arteries
- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication
- **Acute-phase reactants (i.e., erythrocyte sedimentation rate [ESR] or serum C-reactive protein [CRP])**

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for SSc-ILD when the member is currently receiving treatment with **the requested medication**.

Immune checkpoint inhibitor-related inflammatory arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Cytokine release syndrome, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity

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All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Unicentric Castleman disease, Multicentric Castleman disease, and Kaposi-sarcoma herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS)

Authorization of 12 months may be granted for continued treatment in members (including new members) who are using the requested medication for Unicentric Castleman disease, Multicentric Castleman disease, or KSHV-Associated Inflammatory Cytokine Syndrome (KICS) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for continued treatment in members who are using the requested medication for PMR and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Morning stiffness
- Hip or shoulder pain
- Hip or shoulder range of motion
- C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

OTHER

For all indications: **Member has been evaluated for tuberculosis (TB) infection prior to initiation of treatment with a biologic or targeted synthetic drug associated with an increased risk of TB.**

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

APPENDIX

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor



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- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Actemra (Tocilizumab)	Acute Graft Versus Host Disease	Route of Administration: Intravenous 8mg/kg every 2 weeks
Actemra (Tocilizumab)	Castleman Disease (Unicentric or Multicentric)	Route of Administration: Intravenous 8mg/kg every 2 weeks
Actemra (Tocilizumab)	Cytokine Release Syndrome	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart ≥30kg 8mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart
Actemra (Tocilizumab)	Giant Cell Arteritis	Route of Administration: Intravenous ≥18 year(s) 6mg/kg (up to maximum of 600 mg) every 4 weeks
Actemra (Tocilizumab)	Giant Cell Arteritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Actemra (Tocilizumab)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 8mg/kg every 4 weeks
Actemra (Tocilizumab)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Subcutaneous 162mg every week
Actemra (Tocilizumab)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 10mg/kg every 4 weeks ≥30kg 8mg/kg every 4 weeks
Actemra (Tocilizumab)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 3 weeks ≥30kg 162mg every 2 weeks
Actemra (Tocilizumab)	Polymyalgia Rheumatica	Route of Administration: Intravenous 8mg/kg every 4 weeks



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Actemra (Tocilizumab)	Polymyalgia Rheumatica	Route of Administration: Subcutaneous 162mg every week
Actemra (Tocilizumab)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 year(s) 8mg/kg (up to maximum of 800 mg) every 4 weeks
Actemra(Tocilizumab)	Rheumatoid Arthritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Actemra (Tocilizumab)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg every 2 weeks ≥30kg 8mg/kg every 2 weeks
Actemra (Tocilizumab)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 2 weeks ≥30kg 162mg every week
Actemra (Tocilizumab)	Systemic Sclerosis-Associated Interstitial Lung Disease	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Avtozma (Tocilizumab-anoh)	Acute Graft Versus Host Disease	Route of Administration: Intravenous 8mg/kg every 2 weeks
Avtozma (Tocilizumab-anoh)	Castleman Disease (Unicentric or Multicentric)	Route of Administration: Intravenous 8mg/kg every 2 weeks
Avtozma (Tocilizumab-anoh)	Cytokine Release Syndrome	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart ≥30kg 8mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart
Avtozma (Tocilizumab-anoh)	Giant Cell Arteritis	Route of Administration: Intravenous ≥18 year(s) 6mg/kg (up to maximum of 600 mg) every 4 weeks
Avtozma (Tocilizumab-anoh)	Giant Cell Arteritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Avtozma (Tocilizumab-anoh)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 8mg/kg every 4 weeks



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Avtozma (Tocilizumab-anoh)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Subcutaneous 162mg every week
Avtozma(Tocilizumab-anoh)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 10mg/kg every 4 weeks ≥30kg 8mg/kg every 4 weeks
Avtozma (Tocilizumab-anoh)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 3 weeks ≥30kg 162mg every 2 weeks
Avtozma (Tocilizumab-anoh)	Polymyalgia Rheumatica	Route of Administration: Intravenous 8mg/kg every 4 weeks
Avtozma (Tocilizumab-anoh)	Polymyalgia Rheumatica	Route of Administration: Subcutaneous 162mg every week
Avtozma (Tocilizumab-anoh)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 year(s) 8mg/kg (up to maximum of 800 mg) every 4 weeks
Avtozma (Tocilizumab-anoh)	Rheumatoid Arthritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Avtozma (Tocilizumab-anoh)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg every 2 weeks ≥30kg 8mg/kg every 2 weeks
Avtozma (Tocilizumab-anoh)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 2 weeks ≥30kg 162mg every week
Avtozma (Tocilizumab-anoh)	Systemic Sclerosis-Associated Interstitial Lung Disease	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Tofidence (Tocilizumab-bavi)	Acute Graft Versus Host Disease	Route of Administration: Intravenous 8mg/kg every 2 weeks
Tofidence (Tocilizumab-bavi)	Castleman Disease (Unicentric or Multicentric)	Route of Administration: Intravenous 8mg/kg every 2 weeks
Tofidence(Tocilizumab-bavi)	Cytokine Release Syndrome	Route of Administration: Intravenous ≥2 year(s)



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		<30kg 12mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart ≥30kg 8mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart
Tofidence (Tocilizumab-bavi)	Giant Cell Arteritis	Route of Administration: Intravenous ≥18 year(s) 6mg/kg (up to maximum of 600 mg) every 4 weeks
Tofidence (Tocilizumab-bavi)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 8mg/kg every 4 weeks
Tofidence (Tocilizumab-bavi)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 10mg/kg every 4 weeks ≥30kg 8mg/kg every 4 weeks
Tofidence (Tocilizumab-bavi)	Polymyalgia Rheumatica	Route of Administration: Intravenous 8mg/kg every 4 weeks
Tofidence (Tocilizumab-bavi)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 year(s) 8mg/kg (up to maximum of 800 mg) every 4 weeks
Tofidence (Tocilizumab-bavi)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg every 2 weeks ≥30kg 8mg/kg every 2 weeks
Tyenne (Tocilizumab-aazg)	Acute Graft Versus Host Disease	Route of Administration: Intravenous 8mg/kg every 2 weeks
Tyenne (Tocilizumab-aazg)	Castleman Disease (Unicentric or Multicentric)	Route of Administration: Intravenous 8mg/kg every 2 weeks
Tyenne (Tocilizumab-aazg)	Cytokine Release Syndrome	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart ≥30kg 8mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart



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Tyenne(Tocilizumab-aazg)	Giant Cell Arteritis	Route of Administration: Intravenous ≥18 year(s) 6mg/kg (up to maximum of 600 mg) every 4 weeks
Tyenne (Tocilizumab-aazg)	Giant Cell Arteritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Tyenne (Tocilizumab-aazg)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Intravenous 8mg/kg every 4 weeks
Tyenne (Tocilizumab-aazg)	Immune Checkpoint Inhibitor-Related Toxicities	Route of Administration: Subcutaneous 162mg every week
Tyenne (Tocilizumab-aazg)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 10mg/kg every 4 weeks ≥30kg 8mg/kg every 4 weeks
Tyenne (Tocilizumab-aazg)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 3 weeks ≥30kg 162mg every 2 weeks
Tyenne (Tocilizumab-aazg)	Polymyalgia Rheumatica	Route of Administration: Intravenous 8mg/kg every 4 weeks
Tyenne (Tocilizumab-aazg)	Polymyalgia Rheumatica	Route of Administration: Subcutaneous 162mg every week
Tyenne (Tocilizumab-aazg)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 year(s) 8mg/kg (up to maximum of 800 mg) every 4 weeks
Tyenne (Tocilizumab-aazg)	Rheumatoid Arthritis	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
Tyenne (Tocilizumab-aazg)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 year(s) <30kg 12mg/kg every 2 weeks ≥30kg 8mg/kg every 2 weeks
Tyenne(Tocilizumab-aazg)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 year(s) <30kg 162mg every 2 weeks ≥30kg 162mg every week



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Tyenne (Tocilizumab-aazg)	Systemic Sclerosis-Associated Interstitial Lung Disease	Route of Administration: Subcutaneous ≥18 year(s) 162mg every week
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APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

- Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; **December 2025**.
- Avtozma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; **January 2026**.
- tocilizumab-aazg [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC; May 2025.
- tocilizumab-anoh [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2026.
- Tofidence [package insert]. **Jersey City, NJ: Organon & Co.; July 2025**.
- Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC; **August 2025**.
- The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January **15, 2026**.
- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
- Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
- Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
- 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 & Rheumatism*. 2013;65:2499-2512.
- Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *American College of Rheumatology*. 2019;1-18.
- Stone JH, Tuckwell K, Dimonaco S, et al. Efficacy and safety of tocilizumab in patients with giant cell arteritis: Primary and secondary outcomes from a phase 3, randomized, double-blind, placebo-controlled trial. 2016 ACR/ARHP Annual meeting. Abstract number 911.
- Hellmich B, Agueda A, Monti S, et al. 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis*. 2020;79(1):19-30.



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15. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum.* 2010;62(9):2569-81.
16. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med.* 2020 Oct;8(10):e75 [published correction appears in *Lancet Respir Med.* 2021 Mar;9(3):e29]. *Lancet Respir Med.* 2020;8(10):963-974. doi:10.1016/S2213-2600(20)30318-0.
17. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis disease activity and physical function. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed January 23, 2026.
18. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2021;0:1-16.
19. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 23, 2026.
20. 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 Rheumatol.* 2022;74(4):553-569.
21. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6): 1445-86.
22. Rahaghi FF, Hsu VM, Kaner RJ, et al. Expert consensus on the management of systemic sclerosis-associated interstitial lung disease. *Respir Res.* 2023;24(1):6-16.
23. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Ann Rheum Dis.* 2024;0:1-12.

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