



Medical Policy Manual **Draft Revised Policy: Do Not Implement**

Tocilizumab (Actemra®); Tocilizumab-bavi (Tofidence™); Tocilizumab-aazg (Tyenne®)

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.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY**

I. 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.

A. FDA-Approved Indications

1. 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).
2. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA).
3. Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA).
4. Adult patients with giant cell arteritis (GCA).
5. Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function.
6. 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).
7. Hospitalized adult patients 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).

B. Compendial Uses

1. Unicentric Castleman disease
2. Multicentric Castleman disease
3. Oligoarticular juvenile idiopathic arthritis
4. Immune checkpoint inhibitor-related toxicities-inflammatory arthritis
5. Acute graft versus host disease
6. Cytokine release syndrome (other than severe or life-threatening CAR T cell-induced CRS)
7. **Polymyalgia rheumatica**
8. **Moderate to severe rheumatoid arthritis with no previous treatment failure**

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

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

II. DOCUMENTATION



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

- A. Rheumatoid arthritis (RA)
 - 1. Initial requests:
 - i. 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.~~
 - ii. 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).
 - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- B. Articular juvenile idiopathic arthritis
 - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
 - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- C. Systemic juvenile idiopathic arthritis (sJIA)
 - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), ~~including response to therapy.~~
 - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- D. Cytokine release syndrome, immunotherapy-related inflammatory arthritis, and acute graft versus host disease: For 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.
- E. Giant cell arteritis (GCA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- F. Systemic sclerosis-associated interstitial lung disease (SSc-ILD): For initial requests: Result of a chest high-resolution computed tomography (HRCT) study.
- G. **Polymyalgia rheumatica**
 - 1. **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.**
 - 2. **Continuation requests: Chart notes or medical record documentation supporting positive clinical response.**

III. PRESCRIBER SPECIALTIES

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

- A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, ~~and~~ giant cell arteritis, **and polymyalgia rheumatica**: rheumatologist
- B. Systemic sclerosis-associated interstitial lung disease: rheumatologist or pulmonologist
- C. Immune checkpoint inhibitor-related toxicities: oncologist, hematologist, or rheumatologist



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- D. Cytokine release syndrome, unicentric Castleman disease, multicentric Castleman disease, and acute graft versus host disease: oncologist or hematologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.
2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when **either** ~~both~~ of the following criteria are met:
 - ~~i. Member meets either of the following criteria:~~
 - i. Member has been tested for either of the following biomarkers and the test was positive:
 - a. Rheumatoid factor (RF)
 - b. Anti-cyclic citrullinated peptide (anti-CCP)
 - ii. Member has been tested for ALL of the following biomarkers:
 - a. RF
 - b. Anti-CCP
 - c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
 - ~~iii. Member meets either of the following criteria:~~
 - a. ~~Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).~~
 - b. ~~Member has an intolerance or contraindication to methotrexate (see Appendix A).~~

B. Articular juvenile idiopathic arthritis

1. 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.
2. 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:
 - i. 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.
 - ii. 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:
 - a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - b. Presence of erosive disease or enthesitis
 - c. Delay in diagnosis
 - d. Elevated levels of inflammation markers
 - e. Symmetric disease
 - iii. 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:
 - a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
 - b. High disease activity.
 - c. Is judged to be at high risk for disabling joint disease.

C. Systemic juvenile idiopathic arthritis (sJIA)



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1. 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.
2. 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). ~~both of the following criteria are met:~~
 - i. ~~Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).~~
 - ii. ~~Member has had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids.~~

D. 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:

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

E. 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.

F. Cytokine release syndrome

1. Authorization of 1 month may be granted for members 2 years of age or older for treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS).
2. Authorization of 1 month may be granted for treatment of cytokine release syndrome in members with refractory CRS related to blinatumomab therapy.

G. Unicentric Castleman disease

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

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

H. Multicentric Castleman disease

Authorization of 12 months may be granted for treatment of multicentric Castleman disease when both of the following are met:

1. The requested medication will be used as a single agent.
2. The disease has progressed following treatment of relapsed/refractory or progressive disease.

I. Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when then member has severe immunotherapy-related inflammatory arthritis and meets either of the following:

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



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J. 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:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

K. Polymyalgia rheumatica (PMR)

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

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has experienced a disease flare during a taper with systemic corticosteroids.
3. Member has experienced an inadequate response to methotrexate.
4. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

V. CONTINUATION OF THERAPY

A. 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.

B. Articular juvenile idiopathic arthritis

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:

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

C. 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:

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

D. 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:

1. Headaches

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2. Scalp tenderness
3. Tenderness and/or thickening of superficial temporal arteries
4. Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
5. Jaw and/or tongue claudication
6. Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
7. Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
8. Limb claudication

E. 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 Actemra **or Tyenne**.

F. Immune checkpoint inhibitor related toxicity

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.

G. Cytokine release syndrome and acute graft versus host disease

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

H. Unicentric Castleman disease and Multicentric Castleman disease

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 or Multicentric Castleman disease when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

I. 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:

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

J. ~~All other diagnoses~~

~~Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.~~

VI. OTHER

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST PPD] **or** an interferon-release assay [IGRA], ~~or a chest x-ray~~)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.



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* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

Appendix A: Examples of clinical reasons to avoid pharmacologic treatment with methotrexate

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

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Actemra (Tocilizumab), Tofidence (Tocilizumab–bavi)	Acute Graft Versus Host Disease	Route of Administration: Intravenous 8mg/kg every 2 weeks
Actemra (Tocilizumab), Tofidence (Tocilizumab– bavi)	Castleman Disease (Unicentric or Multicentric)	Route of Administration: Intravenous 8mg/kg every 2 weeks
Actemra (Tocilizumab), Tofidence (Tocilizumab–bavi)	Cytokine Release Syndrome	Route of Administration: Intravenous <u>≥2 Years</u> ≥30kg 8mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart <u>≥2 Years</u> <30kg



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		12mg/kg (up to a maximum of 800 mg); no more than 4 total doses given at least 8 hours apart
Actemra (Tocilizumab), Tofidence (Tocilizumab–bavi)	Giant Cell Arteritis	Route of Administration: Intravenous ≥18 Years 6mg/kg (up to maximum of 600 mg) every 4 weeks
Actemra (Tocilizumab)	Giant Cell Arteritis, Systemic Sclerosis- Associated Interstitial Lung Disease	Route of Administration: Subcutaneous ≥18 Years 162mg every week
Actemra (Tocilizumab)	Immunotherapy-Related Inflammatory Arthritis	Route of Administration: Subcutaneous 162mg every week
Actemra (Tocilizumab), Tofidence (Tocilizumab– bavi)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous <u>≥2 Years</u> ≥30kg 8mg/kg every 4 weeks <u>≥2 Years</u> <30kg 10mg/kg every 4 weeks
Actemra (Tocilizumab)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 Years ≥30kg 162mg every 2 weeks <30kg 162mg every 3 weeks
Actemra (Tocilizumab)	Rheumatoid Arthritis	Route of Administration: Subcutaneous ≥18 Years ≥100kg 162mg every week <100kg 162mg every week
Actemra (Tocilizumab), Tofidence (Tocilizumab– bavi)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 Years 8mg/kg (up to maximum of 800 mg) every 4 weeks
Actemra (Tocilizumab), Tofidence (Tocilizumab– bavi)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥2 Years ≥30kg 8mg/kg every 2 weeks ≥2 Years <30kg 12mg/kg every 2 weeks
Actemra (Tocilizumab)	Systemic Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous <u>≥2 Years</u> ≥30kg



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		162mg every week
		<30kg 162mg every 2 weeks

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).

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EFFECTIVE DATE

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