Corporate Medical Policy: Tocilizumab (Actemra®) and Tocilizumab Biosimilars **"Notification"** **POLICY EFFECTIVE JULY 1, 2026**

Restricted Product(s):

- tocilizumab (Actemra®) intravenous (IV) infusion and subcutaneous (SC) injection for administration by a healthcare professional
- tocilizumab-anoh (Avtozma®) intravenous (IV) infusion and subcutaneous (SC) injection for administration by a healthcare professional
- tocilizumab-bavi (Tofidence™) intravenous (IV) infusion for administration by a healthcare professional
- *tocilizumab-aazg (Tyenne®) intravenous (IV) infusion and subcutaneous (SC) injection for administration by a healthcare professional

***preferred agent**

FDA Approved Use:

- For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease Modifying Anti-Rheumatic Drugs (DMARDs) [IV or SC]
- For the treatment of adult patients with giant cell arteritis [IV or SC]
- For the treatment of patients 2 years and older with active polyarticular juvenile idiopathic arthritis [IV or SC]
- For the treatment of patients 2 years and older with active systemic juvenile idiopathic arthritis [IV or SC]
- For the treatment of patients 2 years and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome [IV]
- For slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease [SC]

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of moderately to severely active **rheumatoid arthritis (RA)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. ONE of the following:
        i. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **[medical record documentation required]**; **OR**
        ii. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **[medical record documentation required]**; **OR**

iii. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **[medical record documentation required]**; **OR**
iv. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **[medical record documentation required]**; **OR**
v. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of RA (excluding sample use) **[medical record documentation required]**; **AND**
    1. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **AND**

c. ONE of the following:
    i. The patient has tried and had an inadequate response to an infliximab product AND Simponi Aria® (golimumab) **[medical record documentation required]**; **OR**
    ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to BOTH an infliximab product and Simponi Aria® (golimumab) **[medical record documentation required]**; **OR**
    iii. BOTH of the following:
        1. The prescriber has provided information indicating why ALL of the preferred agents (i.e., infliximab products, Simponi Aria) are not clinically appropriate for the patient **[medical record documentation required]**; **AND**
        2. The prescriber has provided a complete list of previously tried agents for the requested indication **[medical record documentation required]**; **OR**

2. The patient has a diagnosis of **giant cell arteritis (GCA)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to systemic corticosteroids (e.g., prednisone, methylprednisolone) used in the treatment of GCA for at least 7-10 days **[medical record documentation required]**; **OR**
    c. The patient has an intolerance or hypersensitivity to systemic corticosteroids used in the treatment of GCA **[medical record documentation required]**; **OR**
    d. The patient has an FDA labeled contraindication to ALL systemic corticosteroids used in the treatment of GCA **[medical record documentation required]**; **OR**
    e. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of GCA (excluding sample use) **[medical record documentation required]**; **AND**
        i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

3. The patient has a diagnosis of moderately to severely active **polyarticular juvenile idiopathic arthritis (PJIA)**; **AND**
    a. The patient is 2 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to ONE conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA for at least 3-months **[medical record documentation required]**; **OR**
    c. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PJIA **[medical record documentation required]**; **OR**
    d. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PJIA **[medical record documentation required]**; **OR**
    e. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of PJIA (excluding sample use) **[medical record documentation required]**; **AND**
        i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

4. The patient has a diagnosis of active **systemic juvenile idiopathic arthritis (SJIA)**; **AND**
    a. The patient is 2 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to at least ONE NSAID (e.g., ibuprofen, celecoxib) used in the treatment of SJIA for at least 1-month **[medical record documentation required]**; **OR**
    c. The patient has an intolerance or hypersensitivity to NSAIDs used in the treatment of SJIA **[medical record documentation required]**; **OR**
    d. The patient has an FDA labeled contraindication to ALL NSAIDs used in the treatment of SJIA **[medical record documentation required]**; **OR**
    e. The patient has tried and had an inadequate response to another conventional agent (i.e., methotrexate, leflunomide, systemic corticosteroids, azathioprine, cyclosporine, tacrolimus) used in the treatment of SJIA for at least 3-months **[medical record documentation required]**; **OR**
    f. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of SJIA **[medical record documentation required]**; **OR**
    g. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of SJIA **[medical record documentation required]**; **OR**
    h. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of SJIA (excluding sample use) **[medical record documentation required]**; **AND**
        i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

5. The patient has a diagnosis of severe or life-threatening **cytokine release syndrome (CRS)**; **AND**

a. The patient is 2 years of age or older; **AND**
b. The request is for intravenous administration; **AND**
c. The patient has received or will be receiving CAR T cell therapy **[medical record documentation required]**; **AND**
d. ONE of the following:
    i. The CRS was induced by chimeric antigen receptor (CAR) T cell therapy **[medical record documentation required]**; **OR**
    ii. The requested agent is being prescribed proactively to have on-hand, prior to the administration of CAR T cell therapy, if needed for the treatment of CRS **[medical record documentation required]**; **OR**

6. The patient has a diagnosis of **systemic sclerosis-associated interstitial lung disease (SSc-ILD)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. ALL of the following:
        i. The patient has disease onset (e.g., first non-Raynaud symptom) of 5 years or less; **AND**
        ii. The patient has the presence of elevated laboratory inflammatory markers (e.g., acute-phase reactant levels, C-reactive protein, ESR, or platelet count); **AND**
        iii. The patient has active disease, as defined by at least ONE of the following:
            1. Disease duration of 18 months or less; **OR**
            2. Increase in mRSS (modified Rodnan skin score) of at least 3 units over 6 months; **OR**
            3. Involvement of one new body area and an increase in mRSS of at least 2 units over 6 months; **OR**
            4. Involvement of two new body areas within the previous 6 months; **OR**
            5. Presence of at least one tendon friction rub; **AND**
        iv. The diagnosis of SSc-ILD has been confirmed by the presence of characteristic features of interstitial lung disease (ILD) on chest high-resolution computed tomography (HRCT); **AND**
        v. Other known causes of interstitial lung disease have been excluded (e.g., heart failure, drug-induced lung toxicity, recurrent aspiration, pulmonary vascular disease); **AND**
        vi. ONE of the following:
            1. The patient has tried and had an inadequate response to ONE immunosuppressant therapy (e.g., mycophenolate mofetil, cyclophosphamide, azathioprine) used in the treatment of SSc-ILD **[medical record documentation required]**; **OR**
            2. The patient has an intolerance or hypersensitivity to ONE immunosuppressant therapy used in the treatment of SSc-ILD **[medical record documentation required]**; **OR**
            3. The patient has an FDA labeled contraindication to ALL immunosuppressant therapy used in the treatment of SSc-ILD **[medical record documentation required]**; **OR**
    c. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of SSc-ILD (excluding sample use) **[medical record documentation required]**; **AND**

   i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **AND**

7. If the request is for Actemra® (tocilizumab) or a non-preferred tocilizumab biosimilar product [e.g., Avtozma® (tocilizumab-anoh), Tofidence™ (tocilizumab-bavi)], ONE of the following:
   a. The patient has tried and had an inadequate response to the following preferred tocilizumab biosimilar product: Tyenne® (tocilizumab-aazg) **[medical record documentation required]**; **OR**
   b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to Tyenne® (tocilizumab-aazg) that is NOT expected to occur with the requested agent **[medical record documentation required]**; **OR**
   c. The patient has a documented serious adverse event that required medical intervention to Tyenne® (tocilizumab-aazg) that is NOT anticipated with the requested agent **[medical record documentation required]**; **AND**
      i. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form **[medical record documentation required]**; **AND**

8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for RA, JIA, GCA, SSc-ILD; oncologist for CRS; pulmonologist for SSc-ILD) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
9. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent or Otezla®; **AND**
10. The patient does NOT have any FDA labeled contraindications to tocilizumab (Actemra®), tocilizumab-anoh (Avtozma®), tocilizumab-bavi (Tofidence™), or tocilizumab-aazg (Tyenne®); **AND**
11. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB; **AND**
12. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
13. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval:

CRS: 180 days (one-time approval; maximum 4 doses)
All other diagnoses: 365 days (1 year)

Continuation Criteria for Approval:

1. ONE of the following:
   a. The patient has a diagnosis of **systemic sclerosis-associated interstitial lung disease (SSc-ILD)**; **AND**

i. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
ii. The patient would have met initial criteria for approval at the time they started therapy; **OR**

b. For all other indications, **please refer to initial criteria for approval**; **AND**

2. The patient has demonstrated a positive clinical response while using the medication, as demonstrated by improved or maintained annual rate of decline in pulmonary function (i.e., predicted forced vital capacity [FVC% predicted]); **AND**
3. If the request is for Actemra® (tocilizumab) or a non-preferred tocilizumab biosimilar product [e.g., Avtozma® (tocilizumab-anoh), Tofidence™ (tocilizumab-bavi)], ONE of the following:
   a. The patient has tried and had an inadequate response to the following preferred tocilizumab biosimilar product: Tyenne® (tocilizumab-aazg) **[medical record documentation required]**; **OR**
   b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to Tyenne® (tocilizumab-aazg) that is NOT expected to occur with the requested agent **[medical record documentation required]**; **OR**
   c. The patient has a documented serious adverse event that required medical intervention to Tyenne® (tocilizumab-aazg) that is NOT anticipated with the requested agent **[medical record documentation required]**; **AND**
      i. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form **[medical record documentation required]**; **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pulmonologist or rheumatologist for SSc-ILD) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
5. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent or Otezla®; **AND**
6. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
7. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
tocilizumab (Actemra®) intravenous (IV) infusion, subcutaneous (SC) injection	RA in patients ≥ 18 years old	SC: • weight < 100 kg: 162 mg every 2 weeks, up to once weekly based on response • weight ≥ 100 kg: 162 mg once weekly	J3262	CRS: 3,200 All other diagnoses: 20,800

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		IV: 4 mg/kg every 4 weeks, up to 8 mg/kg every 4 weeks based on response, not to exceed 800 mg per infusion		
	GCA in patients ≥ 18 years old	SC: 162 mg once weekly, or every other week may be considered IV: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion		
	PJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 3 weeks • weight ≥ 30 kg: 162 mg every 2 weeks IV: Administered every 4 weeks • weight < 30 kg: 10 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	SJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 2 weeks • weight ≥ 30 kg: 162 mg once weekly IV: Administered every 2 weeks • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	CRS in patients ≥ 2 years old (IV)	IV: Up to 4 doses with interval between consecutive doses of at least 8 hrs, not to exceed 800 mg per infusion • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	SSc-ILD in patients ≥ 18 years old (SC)	SC: 162 mg once weekly		
tocilizumab-anoh (Avtozma®) intravenous (IV) infusion, subcutaneous (SC) injection	RA in patients ≥ 18 years old	SC: • weight < 100 kg: 162 mg every 2 weeks, up to once weekly based on response • weight ≥ 100 kg: 162 mg once weekly IV: 4 mg/kg every 4 weeks, up to 8 mg/kg every 4 weeks based on response, not to exceed 800 mg per infusion	Q5156	CRS: 3,200 All other diagnoses: 20,800
	GCA in patients ≥ 18 years old	SC: 162 mg once weekly, or every other week may be considered IV: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion		
	PJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 3 weeks • weight ≥ 30 kg: 162 mg every 2 weeks IV: Administered every 4 weeks • weight < 30 kg: 10 mg/kg • weight ≥ 30 kg: 8 mg/kg		

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	SJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 2 weeks • weight ≥ 30 kg: 162 mg once weekly IV: Administered every 2 weeks • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	CRS in patients ≥ 2 years old (IV)	IV: Up to 4 doses with interval between consecutive doses of at least 8 hrs, not to exceed 800 mg per infusion • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	SSc-ILD in patients ≥ 18 years old (SC)	SC: 162 mg once weekly		
tocilizumab-bavi (Tofidence™) intravenous (IV) infusion	RA in patients ≥ 18 years old	IV: 4 mg/kg every 4 weeks, up to 8 mg/kg every 4 weeks based on response, not to exceed 800 mg per infusion	Q5133	CRS: 3,200 All other diagnoses: 20,800
	GCA in patients ≥ 18 years old	IV: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion		
	PJIA in patients ≥ 2 years old	IV: Administered every 4 weeks • weight < 30 kg: 10 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	SJIA in patients ≥ 2 years old	IV: Administered every 2 weeks • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	CRS in patients ≥ 2 years old (IV)	IV: Up to 4 doses with interval between consecutive doses of at least 8 hrs, not to exceed 800 mg per infusion • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
tocilizumab-aazg (Tyenne®) intravenous (IV) infusion, subcutaneous (SC) injection	RA in patients ≥ 18 years old	SC: • weight < 100 kg: 162 mg every 2 weeks, up to once weekly based on response • weight ≥ 100 kg: 162 mg once weekly IV: 4 mg/kg every 4 weeks, up to 8 mg/kg every 4 weeks based on response, not to exceed 800 mg per infusion	Q5135	CRS: 3,200 All other diagnoses: 20,800
	GCA in patients ≥ 18 years old	SC: 162 mg once weekly, or every other week may be considered IV: 6 mg/kg every 4 weeks, not to exceed 600 mg per infusion		
	PJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 3 weeks • weight ≥ 30 kg: 162 mg every 2 weeks IV: Administered every 4 weeks • weight < 30 kg: 10 mg/kg • weight ≥ 30 kg: 8 mg/kg		

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	SJIA in patients ≥ 2 years old	SC: • weight < 30 kg: 162 mg every 2 weeks • weight ≥ 30 kg: 162 mg once weekly IV: Administered every 2 weeks • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	CRS in patients ≥ 2 years old (IV)	IV: Up to 4 doses with interval between consecutive doses of at least 8 hrs, not to exceed 800 mg per infusion • weight < 30 kg: 12 mg/kg • weight ≥ 30 kg: 8 mg/kg		
	SSc-ILD in patients ≥ 18 years old (SC)	SC: 162 mg once weekly		

***Maximum units allowed for duration of approval**

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care & Research*. 2021;73(7):924-39.
2. van den Hoogen F, Khanna D, Fransen J, et al. 2013 classification criteria for systemic sclerosis: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Ann Rheum Dis*. 2013;72(11):1747-55.
3. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2020;8(10):963-74.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

July 2026: Criteria change: For CRS: Adjusted criteria to allow for proactive prescribing of tocilizumab in anticipation of possible CRS with documented confirmation of planned or current treatment with CAR-T therapy; Changed maximum units to reflect a maximum of four 800 mg doses, and extended duration of approval to 180 days (maximum of 4 doses) to align with CAR-T authorization timeframe. For RA, GCA, PJIA, SJIA, and SSc-ILD: Added allowance for patients currently established on a biologic or systemic immunomodulator agent that is FDA approved for treatment of the requested indication for those who have had positive clinical benefit from use of the biologic or systemic immunomodulator agent. Other minor formatting changes made throughout policy for clarity with no change to intent. **Policy notification given 5/1/2026 for effective date 7/1/2026**.
April 2026: Criteria update: For SSc-ILD indication, updated trial and failure criteria to separate out intolerance/hypersensitivity criteria from FDA labeled contraindication criteria for clarity. Updated continuation criteria to differentiate between diagnoses and added redirection to initial criteria for all other indications except SSc-ILD (continuation criteria to only apply to SSc-ILD indication).
November 2025: Criteria change: Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.
October 2025: Coding change (Avtozma): Added HCPCS code Q5156 (1 unit per 1 mg) to dosing reference table effective 10/1/2025; deleted C9399, J3490, and J3590 termed 9/30/2025.
July 2025: Criteria change: Added newly approved tocilizumab biosimilar Avtozma (tocilizumab-anoh) to policy for the same FDA approved indications as Actemra IV/SC (RA, GCA, PJIA, SJIA) and with the same coverage criteria requirements. For Avtozma, added additional corresponding criteria as a non-preferred tocilizumab biosimilar product with requirement of trial and failure of Tyenne. Added drug to SOC criteria and added associated dosing and maximum units, and HCPCS codes C9399, J3490, and J3590 to FDA label reference table.
May 2025: Criteria change: Added requirement within continuation criteria for trial and failure of a preferred tocilizumab biosimilar product (i.e., Tyenne [tocilizumab-aazg]) and listed non-preferred tocilizumab products to include Actemra (tocilizumab) and Tofidence (tocilizumab-bavi). Included within trial and failure criteria in continuation section the allowance for presence of a documented serious adverse event requiring medical intervention from the preferred tocilizumab biosimilar product that is not anticipated with the requested non-preferred tocilizumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. **Policy notification given 3/1/2025 for effective date 5/1/2025**.
January 2025: Criteria change: Changed requirement for trial and failure of a preferred tocilizumab biosimilar product to include Tyenne (tocilizumab-aazg) and adjusted non-preferred tocilizumab products to include Actemra (tocilizumab) and Tofidence (tocilizumab-bavi). Updated trial and failure criteria to also allow for presence of a documented serious adverse event requiring medical intervention from the preferred tocilizumab biosimilar product that is not anticipated with the requested non-preferred tocilizumab product, with required submission of an FDA MedWatch Adverse Event Reporting Form. **Policy notification given 11/1/2024 for effective date 1/1/2025**.

October 2024: Coding change (Tyenne): Added HCPCS code Q5135 to dosing reference table effective 10/1/2024; deleted C9399, J3490, and J3590 termed 9/30/2024.
June 2024: Criteria change: Added newly approved tocilizumab biosimilar Tyenne (tocilizumab-aazg) to policy for the same FDA approved indications as Actemra IV/SC and with the same coverage criteria requirements. Added newly approved tocilizumab biosimilar Tofidence (tocilizumab-bavi) to policy for the same FDA approved indications as Actemra IV with the same coverage criteria requirements by indication. For Tofidence, added additional corresponding criteria as a non-preferred tocilizumab biosimilar product with requirement of trial and failure of Actemra or Tyenne. Added drugs to SOC criteria and added associated dosing and maximum units, and HCPCS codes Q5133 for Tofidence and C9399, J3490, and J3590 for Tyenne to FDA label reference table. Changed policy name to "Tocilizumab (Actemra®) and Tocilizumab Biosimilars" from "Tocilizumab (Actemra®)".
September 2023: Criteria change: For PJIA: Adjusted list of tried and failed conventional agents. For SJIA: Adjusted tried and failed agents to at least one NSAID. Separated out intolerance/hypersensitivity criteria from FDA labeled contraindication criteria for clarity.
February 2023: Criteria update: Added criteria to allow for the prescriber indicating the preferred agents (i.e., infliximab products, Simponi Aria) are not clinically appropriate for the patient for rheumatoid arthritis indication. Updated references.
January 2023: Criteria change: Changed requirement for trial and failure of preferred agents for rheumatoid arthritis to include both an infliximab product AND Simponi Aria. **Policy notification given 11/1/2022 for effective date 1/1/2023**.
July 2022: Criteria update: Removed criterion point requiring subcutaneous administration for GCA indication.
May 2022: Criteria update: Updated max units in dosing table to 20800 for Actemra.
August 2021: Criteria change: Removed criteria points regarding medication history indicating use of another biologic immunomodulator agent FDA labeled for the treatment of the same condition. **Policy notification given 6/1/2021 for effective date 8/1/2021**.
June 2021: Criteria change: Medical record documentation required for all indications.
April 2021: Criteria change: Addition of new indication for systemic sclerosis-associated interstitial lung disease.
April 2021: Criteria change: Addition of criteria for history of use of another biologic immunomodulator agent for the same indication; RA: added requirement of trial of methotrexate or another conventional agent; GCA: added requirement of trial of systemic corticosteroids; PJIA: added requirement of trial of one conventional agent; SJIA: added requirement of trial with NSAIDs or another conventional agent; removed requirements for laboratory values and no active infection present; added requirements to be prescribed by or in consultation with a specialist, that patient has no FDA labeled contraindications, and for TB testing; added maximum units; medical policy formatting change. **Policy notification given 2/26/2021 for effective date 4/28/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.