BlueCross BlueShield
Federal Employee Program

ACTEMRA (tocilizumab)
TOFIDENCE* (tocilizumab-bavi)
TYENNE (tocilizumab-aazg)

*These medications are currently pending tier determination and may not be available at this time

Pre - PA Allowance

None

Prior-Approval Requirements

The use of Actemra or its biosimilars for the treatment of COVID-19 should be billed under the medical benefit.

Diagnoses

Patient must have **ONE** of the following:

1. Active Polyarticular Juvenile Idiopathic Arthritis (PJIA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
    c. Prescriber will be dosing the patient within the FDA labeled dose of **ONE** of the following:
        i. IV infusion:
            1) Patients less than 30 kg weight – 10 mg/kg every 4 weeks
            2) Patients at or above 30 kg weight – 8 mg/kg every 4 weeks
        ii. Subcutaneous administration
            1) Patients less than 30 kg weight – 162 mg once every three weeks
            2) Patients at or above 30 kg weight – 162 mg once every two weeks
    d. Subcutaneous administration **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
    e. IV infusion **only:** Patient has had an inadequate response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

2. Active Systemic Juvenile Idiopathic Arthritis (SJIA)
    a. 2 years of age or older

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b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
    i. IV infusion:
        1) Patients less than 30 kg weight – 12 mg/kg every 2 weeks
        2) Patients at or above 30 kg weight – 8 mg/kg every 2 weeks
    ii. Subcutaneous administration:
        1) Patients less than 30 kg weight – 162 mg once every 2 weeks
        2) Patients at or above 30 kg weight – 162 mg once every week

AND ONE of the following for SJIA:
a. Inadequate treatment response to at least a 2 week trial of corticosteroids
b. Inadequate treatment response to at least a 3 month trial of methotrexate or leflunomide

3. Moderately to severely active Rheumatoid Arthritis (RA)
    a. 18 years of age and older
    b. Inadequate response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (See Appendix 1)
    c. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion: 8 mg/kg every 4 weeks
        ii. Subcutaneous administration: 162 mg every week
    d. Subcutaneous administration **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
    e. IV infusion **only:** Patient has had an inadequate response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

4. Giant Cell Arteritis
    a. 18 years of age and older
    b. Inadequate treatment response to at least a 3 month trial of corticosteroids
    c. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion: 6 mg/kg every 4 weeks

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ii. Subcutaneous administration: 162 mg every week

5. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
    a. 18 years of age and older
    b. **NO** IV administration
    c. Prescriber will be dosing the patient within the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 162 mg every week

6. Cytokine release syndrome (CRS)
    a. 2 years of age and older
    b. Chimeric antigen receptor (CAR) T cell-induced CRS
    c. Syndrome is severe or life-threatening
    d. **NO** subcutaneous administration
    e. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion: Patients less than 30 kg weight – 12 mg/kg with up to 3 additional doses administered at least 8 hours apart
        ii. IV infusion: Patients at or above 30 kg weight – 8 mg/kg with up to 3 additional doses administered at least 8 hours apart

7. Unicentric Castleman's Disease
    a. Disease is relapsed or refractory
    b. Prescribed as a single agent therapy
    c. Patient is HIV negative
    d. Patient is human herpesvirus-8 negative
    e. **NO** subcutaneous administration
    f. Prescriber will be dosing the patient within the maintenance dose of the following:
        i. IV infusion: 8 mg/kg every 4 weeks

8. Multicentric Castleman's Disease
    a. Disease has progressed following treatment of relapsed/refractory or progressive disease
    b. Prescribed as a single agent therapy
    c. **NO** subcutaneous administration

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d. Prescriber will be dosing the patient within the maintenance dose of the following:
    i. IV infusion: 8 mg/kg every 2 weeks

AND ALL of the following for all indications:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
3. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 1)
5. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Route of Administration	Diagnosis	Strength	Quantity
Subcutaneous	Giant cell arteritis Rheumatoid Arthritis Systemic Sclerosis-Associated Interstitial Lung Disease	162 mg/ 0.9 mL	12 units per 84 days
	Polyarticular Juvenile Idiopathic Arthritis	162 mg/ 0.9 mL	Weight < 30kg 4 units per 84 days Weight ≥ 30kg 6 units per 84 days
	Systemic Juvenile Idiopathic Arthritis	162 mg/ 0.9 mL	Weight < 30kg 6 units per 84 days Weight ≥ 30kg 12 units per 84 days
IV	Cytokine Release Syndrome	80 mg **OR** 200 mg **OR** 400 mg	8 single-dose vials per Lifetime
	Giant cell arteritis	80 mg 200 mg 400 mg	6 mg/kg every 4 weeks

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	Polyarticular Juvenile Idiopathic Arthritis	80 mg 200 mg 400 mg	Weight < 30kg 10 mg/kg every 4 weeks Weight ≥ 30kg 8 mg/kg every 4 weeks
	Systemic Juvenile Idiopathic Arthritis	80 mg 200 mg 400 mg	Weight < 30kg 12 mg/kg every 2 weeks Weight ≥ 30kg 8 mg/kg every 2 weeks
	Rheumatoid Arthritis	80 mg 200 mg 400 mg	8 mg/kg every 4 weeks
	Unicentric Castleman's Disease	80 mg 200 mg 400 mg	8 mg/kg every 4 weeks
	Multicentric Castleman's Disease	80 mg 200 mg 400 mg	8 mg/kg every 2 weeks

Duration 12 months

Prior – Approval *Renewal* Requirements

The use of Actemra or its biosimilars for the treatment of COVID-19 should be billed under the medical benefit.

Diagnoses

Patient must have **ONE** of the following:

1. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
    a. 2 years of age or older
    b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion:
            1) Patients less than 30 kg weight – 10 mg/kg every 4 weeks
            2) Patients at or above 30 kg weight – 8 mg/kg every 4 weeks
        ii. Subcutaneous administration
            1) Patients less than 30 kg weight – 162 mg once every 3 weeks
            2) Patients at or above 30 kg weight – 162 mg once every 2 weeks

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c. Subcutaneous administration **only:** Patient **MUST**** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Systemic Juvenile Idiopathic Arthritis (SJIA)
    a. 2 years of age or older
    b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion:
            1) Patients less than 30 kg weight – 12 mg/kg every 2 weeks
            2) Patients at or above 30 kg weight – 8 mg/kg every 2 weeks
        ii. Subcutaneous administration:
            1) Patients less than 30 kg weight – 162 mg once every 2 weeks
            2) Patients at or above 30 kg weight – 162 mg once every week

3. Rheumatoid Arthritis (RA)
    a. 18 years of age and older
    b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion: 8 mg/kg every 4 weeks
        ii. Subcutaneous administration: 162 mg every week
    c. Subcutaneous administration **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Giant Cell Arteritis
    a. 18 years of age and older
    b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of **ONE** of the following:
        i. IV infusion: 6 mg/kg every 4 weeks
        ii. Subcutaneous administration: 162 mg every week

5. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
    a. 18 years of age and older

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b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of the following:
    i. Subcutaneous administration: 162 mg every week

6. Unicentric Castleman's Disease
    a. Prescriber will be dosing the patient within the maintenance dose of the following:
        i. IV infusion: 8 mg/kg every 4 weeks

7. Multicentric Castleman's Disease
    a. Prescriber will be dosing the patient within the maintenance dose of the following:
        i. IV infusion: 8 mg/kg every 2 weeks

AND ALL of the following for all indications:
1. Condition has improved or stabilized
2. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 1)
4. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity
NO renewal for Cytokine release syndrome (CRS)

Route of Administration	Diagnosis	Strength	Quantity
Subcutaneous	Giant cell arteritis	162 mg/0.9 mL	12 units per 84 days
	Rheumatoid Arthritis		
	Systemic Sclerosis-Associated Interstitial Lung Disease		
	Polyarticular Juvenile Idiopathic Arthritis	162 mg/0.9 mL	Weight < 30kg 4 units per 84 days Weight ≥ 30kg 6 units per 84 days

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	Systemic Juvenile Idiopathic Arthritis	162 mg/0.9 mL	Weight < 30kg 6 units per 84 days Weight ≥ 30kg 12 units per 84 days
IV	Giant cell arteritis	80 mg 200 mg 400 mg	6 mg/kg every 4 weeks
	Polyarticular Juvenile Idiopathic Arthritis	80 mg 200 mg 400 mg	Weight < 30kg 10 mg/kg every 4 weeks Weight ≥ 30kg 8 mg/kg every 4 weeks
	Systemic Juvenile Idiopathic Arthritis	80 mg 200 mg 400 mg	Weight < 30kg 12 mg/kg every 2 weeks Weight ≥ 30kg 8 mg/kg every 2 weeks
	Rheumatoid Arthritis	80 mg 200 mg 400 mg	8 mg/kg every 4 weeks
	Unicentric Castleman's Disease	80 mg 200 mg 400 mg	8 mg/kg every 4 weeks
	Multicentric Castleman's Disease	80 mg 200 mg 400 mg	8 mg/kg every 2 weeks

Duration 18 months

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

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Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity

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7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	*must try **ONE** preferred product: Humira** Enbrel Xeljanz	*must try **ONE** preferred product: Enbrel Humira**
Rheumatoid Arthritis (RA)	*must try **ONE** preferred product: Humira** Enbrel Rinvoq Xeljanz/Xeljanz XR	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)