BlueCross BlueShield Federal Employee Program

ORENCIA
(abatacept)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

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

1. Moderately to severely active rheumatoid arthritis (RA)
    a. 18 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 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Orencia SC **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. Orencia IV **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 2) if adjudicated through the pharmacy benefit

2. Active Juvenile Rheumatoid Arthritis (JRA)/ 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 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Orencia SC **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. Orencia IV **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 2) if adjudicated through the pharmacy benefit

3. Active Psoriatic Arthritis (PsA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1000 mg every 4 weeks
        ii. Subcutaneous administration: 125 mg every week
    d. Orencia SC **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. Orencia IV **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 2) if adjudicated through the pharmacy benefit

4. Prophylaxis of acute graft versus host disease (aGVHD)
    a. 2 years of age or older
    b. Used in combination with a calcineurin inhibitor and methotrexate
    c. Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor
    d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: Age 6 and older – 10 mg/kg (maximum dose 1,000 mg) on the day before transplantation (Day -1), then Days 5, 14, and 28 after transplantation
        ii. IV infusion: Ages 2 to 5 – 15 mg/kg on the day before transplantation (Day -1), then 12 mg/kg on Days 5, 14, and 28 after transplantation

AND ALL of the following:

1. Tuberculin skin test conducted to rule out tuberculosis
    a. Patients testing positive in tuberculosis screening must be treated by standard medical practice currently or completed prior to therapy
2. Hepatitis B virus (HBV) has been ruled out or treatment initiated

3. **NO** active infection
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
5. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Orencia SC	Polyarticular Juvenile Idiopathic Arthritis	50 mg 87.5 mg 125 mg	12 units per 84 days
	Psoriatic Arthritis (**Age 2-17 only**)		
	Psoriatic Arthritis (**Age 18+ only**)	125 mg	12 units per 84 days
	Rheumatoid Arthritis		
Orencia IV	Prophylaxis of acute graft versus host disease	250 mg	16 vials
	Polyarticular Juvenile Idiopathic Arthritis	250 mg	56 vials every 365 days (1000 mg at Week 0, 2, 4 then every 4 weeks)
	Psoriatic Arthritis (**Age 18+ only**)		
	Rheumatoid Arthritis		

Duration 3 months for Prophylaxis of acute graft versus host disease
12 months for all other diagnoses

Prior – Approval *Renewal* Requirements

Diagnoses

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

1. Rheumatoid Arthritis (RA) in adults
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the

following:
   i. IV infusion: 1000 mg every 4 weeks
   ii. Subcutaneous administration: 125 mg every week
c. Orencia SC **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. Juvenile Rheumatoid Arthritis (JRA)/Polyarticular Juvenile Idiopathic Arthritis (pJIA)
   a. 2 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. IV infusion: 1000 mg every 4 weeks
      ii. Subcutaneous administration: 125 mg every week
   c. Orencia SC 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)

3. Psoriatic Arthritis (PsA)
   a. 2 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. IV infusion: 1000 mg every 4 weeks
      ii. Subcutaneous administration: 125 mg every week
   c. Orencia SC **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)

AND ALL of the following:
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 2)
4. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

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ORENCIA (abatacept)

Medication	Diagnosis	Strength	Quantity
Orencia SC	Polyarticular Juvenile Idiopathic Arthritis	50 mg 87.5 mg 125 mg	12 units per 84 days
	Psoriatic Arthritis (**Age 2-17 only**)		
	Psoriatic Arthritis (**Age 18+ only**)	125 mg	12 units per 84 days
	Rheumatoid Arthritis		
Orencia IV	Prophylaxis of acute graft versus host disease	**NO** renewal	**NO** renewal
	Polyarticular Juvenile Idiopathic Arthritis	250 mg	12 vials every 84 days
	Psoriatic Arthritis (**Age 18+ only**)		
	Rheumatoid Arthritis		

Duration 18 months

Appendix 1 – 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
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 2 - 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

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 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	*must try **TWO** preferred products: Actemra SC Enbrel Humira** Rinvoq Xeljanz	*must try **ONE** preferred product: Enbrel Humira**
Psoriatic Arthritis (PsA)	*must try **TWO** preferred products: Enbrel Humira** Otezla Rinvoq Skyrizi Stelara (SC) Taltz Tremfya Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**
Rheumatoid Arthritis (RA)	*must try **TWO** preferred products: Actemra SC Enbrel Humira** Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**

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