BlueCross BlueShield
Federal Employee Program

SIMPONI / SIMPONI ARIA
(golimumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

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

Simponi and Simponi Aria

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 1)
    c. If **NO** contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX) (See Appendix 2)
    d. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
        ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
    e. Simponi **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
    f. Simponi Aria **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

2. Active Psoriatic Arthritis (PsA)
    a. Simponi **only:** 18 years of age or older
    b. Simponi Aria **only:** 2 years of age or older
    c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
    d. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
        ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks

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e. Simponi **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
f. Simponi Aria **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

3. Active Ankylosing Spondylitis (axial spondyloarthritis)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least 2 different NSAIDS (non-steroidal anti-inflammatory drugs) over a 4-week period in total at maximum recommended or tolerated dose
   c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
      i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
      ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
   d. Simponi **only:** Patient **MUST** have tried the preferred products (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
   e. Simponi Aria **only:** Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

Simponi ONLY

1. Ulcerative Colitis (UC)
   a. 18 years of age or older

   AND ONE of the following for **UC**:
   a. Corticosteroid dependence (member requires continuous corticosteroids or cannot be successfully tapered off of corticosteroids without return of UC symptoms)
   b. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 3)

   AND ALL of the following for **UC**:
   a. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 4 weeks
   b. Patient **MUST** have tried Humira if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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Simponi Aria ONLY

1. 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 drug (DMARD) (see Appendix 1)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg/m^2 (based on body surface area) every 8 weeks
    d. Patient has had an inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 1) if adjudicated through the pharmacy benefit

AND ALL of the following for **BOTH Simponi** and **Simponi Aria**:

a. 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
b. 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.
c. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
d. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
e. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Simponi	Ankylosing Spondylitis	50 mg	3 units per 84 days
	Psoriatic Arthritis		
	Rheumatoid Arthritis		
	Ulcerative Colitis	100 mg*	15 units per 365 days (Loading dose of 200mg at week 0, followed by 100mg at week 2, then maintenance dosing

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			of 100mg every 4 weeks)
Simponi Aria	Ankylosing Spondylitis	50 mg	2mg/kg every 8 weeks (Loading dose of 2mg/kg at weeks 0 and 4, and every 8 weeks thereafter)
	Psoriatic Arthritis		
	Rheumatoid Arthritis		
	Polyarticular Juvenile Idiopathic Arthritis	50 mg	80 mg/m^2 every 8 weeks (Loading dose of 80 mg/m^2 at weeks 0 and 4, and every 8 weeks thereafter)

***Simponi 100mg for use only in patients with a diagnosis of UC**

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

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

Simponi and Simponi Aria

1. Rheumatoid Arthritis (RA)
    a. 18 years of age or older
    b. Used in combination with methotrexate (MTX) unless contraindication or intolerance (see Appendix 2)
    c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
        ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
    d. Simponi **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Psoriatic Arthritis (PsA)
    a. Simponi **only:** 18 years of age or older

b. Simponi Aria **only:** 2 years or age or older
c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
    i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
    ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
d. Simponi **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Ankylosing Spondylitis (or axial spondyloarthritis)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. **Simponi Aria** IV infusion: 2mg/kg every 8 weeks
        ii. **Simponi** Subcutaneous administration: 50 mg every 4 weeks
    c. Simponi **only:** Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi ONLY

1. Ulcerative Colitis (UC)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 100 mg every 4 weeks
    c. Patient **MUST** have tried Humira if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Simponi Aria ONLY

1. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
    a. 2 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg/m^2 (based on body surface area) every 8 weeks

AND ALL of the following for **BOTH Simponi** and **Simponi Aria**:
a. Condition has improved or stabilized
b. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))

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c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
d. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Simponi	Ankylosing Spondylitis	50 mg	3 units per 84 days
	Psoriatic Arthritis		
	Rheumatoid Arthritis		
	Ulcerative Colitis	100 mg*	3 units per 84 days
Simponi Aria	Ankylosing Spondylitis	50 mg	2mg/kg every 8 weeks
	Psoriatic Arthritis		
	Rheumatoid Arthritis		
	Polyarticular Juvenile Idiopathic Arthritis	50 mg	80 mg/m^2 every 8 weeks

***Simponi 100mg for use only in patients with a diagnosis of UC**

Duration 18 months

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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

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

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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 3 – List of Conventional Therapies

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis: a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine

Appendix 4 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ankylosing spondylitis (AS)	*must try **TWO** preferred products: Enbrel Humira** Rinvoq Taltz	*must try **ONE** preferred product: Enbrel Humira**

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Psoriatic arthritis (PsA)	*must try **TWO** preferred products: Enbrel Humira** Otezla Rinvoq Stelara (SC) Skyrizi 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**
Ulcerative colitis (UC)***	*must try **Humira** first: Humira** Rinvoq Skyrizi Stelara (SC)	Humira**

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

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