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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	January 1, 2014
Subject:	Simponi / Simponi ARIA	**Page:**	1 of 15

Last Review Date: September 6, 2024

Simponi / Simponi Aria

Description

Simponi / Simponi Aria (golimumab)

Background
Tumor necrosis factor-alpha (TNF-α) is a protein produced by the body's immune system. In certain autoimmune diseases, such as rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis, there is an overproduction of TNF-α which causes the immune system to attack parts of the body (1). Simponi and Simponi Aria work by binding to the tumor necrosis factor (TNF), preventing the binding of TNF-α to its receptors and reducing inflammation (2-3).

Regulatory Status
FDA-approved indications: Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of: (2-3)

1. Rheumatoid Arthritis (RA) - **Simponi** and **Simponi Aria**, in combination with methotrexate, are indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis

2. Psoriatic Arthritis (PsA) - **Simponi** and **Simponi Aria**, alone or in combination with methotrexate other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis. Simponi is only indicated in adults while Simponi Aria is indicated in patients 2 years of age and older

3. Ankylosing Spondylitis (AS) - **Simponi** and **Simponi Aria** alone or in combination with methotrexate other non-biologic Disease-modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of adult patients with active ankylosing spondylitis (and axial spondyloarthritis)

4. Ulcerative Colitis (UC) - **Simponi** is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, achieving and sustaining clinical remission in induction responders

5. Polyarticular Juvenile Idiopathic Arthritis (pJIA) - **Simponi Aria** is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Simponi and Simponi Aria carry boxed warnings regarding serious infections and malignancies. Because Simponi and Simponi Aria suppress the immune system, patients are at a greater risk for getting serious infections leading to hospitalization or death, including tuberculosis (TB), invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers (2-3).

Patients should be screened for latent tuberculosis infection. Patients at risk for hepatitis B virus (HBV) infection should be evaluated for evidence of prior HBV infection. Hepatitis B virus carriers should be monitored for reactivation during and several months after therapy. Simponi and Simponi Aria should not be used in combination with other biologic agents. Simponi and Simponi Aria should not be initiated in patients with an active infection. Simponi and Simponi Aria should be discontinued if a patient develops a serious infection during treatment (2-3).

For the treatment of RA, Simponi and Simponi Aria should be used with methotrexate (MTX) or other conventional disease modifying anti-rheumatic drugs (DMARD). Since the presence or absence of concomitant MTX did not appear to influence the efficacy or safety of Simponi and Simponi Aria in the treatment of PsA or AS, Simponi and Simponi Aria can be used with or without MTX in the treatment of PsA and AS (2-3).

An increased risk of serious infections has been seen in clinical RA trials of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit; therefore, use of

Simponi and Simponi Aria with abatacept or anakinra is not recommended. A higher rate of serious infections has also been observed in RA patients treated with rituximab who received subsequent treatment with a TNF-blocker. The concomitant use of Simponi and Simponi Aria with biologics is not recommended because of the possibility of an increased risk of infection (2-3).

The safety and effectiveness of Simponi in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have been established in pediatric patients 2 years of age and older (2-3).

Related policies
Cimzia, Enbrel, Humira, Infliximab

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Simponi and Simponi Aria may be considered **medically necessary** if the conditions indicated below are met.

Simponi and Simponi Aria may be considered **investigational** for all other indications.

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
    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)

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 *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)]

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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Simponi	Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis	50 mg	3 units per 84 days
	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 of 100mg every 4 weeks)
Simponi Aria	Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis	50 mg	2mg/kg every 8 weeks (Loading dose of 2mg/kg at weeks 0 and 4, and every 8 weeks thereafter)
	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* Limits

Quantity

Medication	Diagnosis	Strength	Quantity
Simponi	Ankylosing Spondylitis Psoriatic Arthritis Rheumatoid Arthritis	50 mg	3 units per 84 days
	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

Rationale

Summary

Simponi and Simponi Aria are tumor necrosis factor (TNF) blockers indicated for the treatment of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Simponi is also indicated in adult patients with ulcerative colitis (UC), and Simponi Aria is indicated in patients with polyarticular juvenile idiopathic arthritis (pJIA). Simponi and Simponi Aria carry boxed warnings regarding the increased risk of serious infections and malignancies. The safety and effectiveness of Simponi in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Simponi Aria for active polyarticular juvenile idiopathic arthritis (pJIA) and psoriatic arthritis (PsA) have been established in pediatric patients 2 years of age and older (2-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Simponi and Simponi Aria while maintaining optimal therapeutic outcomes.

References

1. American College of Rheumatology. American College of Rheumatology website. http://www.rheumatology.org/practice/clinical/patients/medications/anti_tnf.asp.
2. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
3. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.

Policy History

Date	Action
October 2013	Addition to PA
December 2013	Annual editorial review by the PMPC

March 2014	Addition of other conventional DMARD to RA and remove moderate to severely active from renewal secondary to requiring improvement and the addition of Simponi ARIA
September 2014	Editorial review and reference update and renewal limit to 18 months
September 2016	Annual editorial review and reference update Addition of not to be used in combination with any other biologic DMARD or targeted synthetic DMARD Addition of not given concurrently with live vaccines per SME
December 2016	Annual editorial review and reference update Addition of age criteria to renewal criteria Addition of initiation criteria to RA: Contraindication, intolerance, or inadequate response to at least a 3-month trial of methotrexate therapy despite adequate dosing and if no contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX) Addition of initiation criteria to PsA for the patient to have one of the following: Contraindication, intolerance, or inadequate treatment response to at least a 3-month trial of methotrexate, sulfasalazine, or leflunomide, active enthesitis and/or dactylitis (sausage digit), or predominantly axial disease (extensive spinal involvement) Addition of initiation criteria to AS: Contraindication, intolerance, or inadequate treatment response to at least 2 different NSAIDS (non-steroidal anti-inflammatory drugs) over a 4-week period in total at maximum recommended or tolerated dose Addition of initiation criteria to UC, patient must have ONE of the following: corticosteroid dependence (member requires continuous corticosteroids or cannot be successfully tapered off of corticosteroids without return of UC symptoms), OR inadequate response, intolerance, or contraindication to at least one conventional therapy
March 2017	Annual review
December 2017	Annual editorial review and reference update Addition of dosing limit requirements Addition of PsA and Ankylosing Spondylitis for Simponi Aria Change of RA requirement of MTX for 3 month trial to DMARD 3 month trial
March 2018	Annual editorial review Addition of Appendix 1

June 2018	Change of requirements to initiation criteria - For diagnosis of UC: inadequate response, intolerance or contraindication to at least ONE conventional DMARD - For diagnosis of PsA: inadequate response, intolerance or contraindication to at least ONE conventional DMARD Addition of Appendix 2 & 3 Removal of active enthesitis and/or dactylitis (sausage digit) and predominantly axial disease (extensive spinal involvement) from PsA
September 2018	Annual editorial review and reference update
March 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred product
March 2020	Annual review and reference update
August 2020	Clarifying language added to pharmacy benefit
September 2020	Annual review
October 2020	Addition of indication for Simponi Aria: polyarticular juvenile idiopathic arthritis. Also changed age for Simponi Aria for PsA to 2 and older
December 2020	Added Appendix 4 with a list of preferred medications based on diagnosis and plan. Added PA quantity limits for Simponi. Added initiation requirement for Simponi Aria to t/f a biologic or targeted synthetic DMARD per FEP
January 2021	Updated t/f options for Simponi UC diagnosis to require trial of Humira first per FEP
March 2021	Annual review and reference update. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.
April 2021	Updated Quantity Limit chart to include loading dose of Simponi Aria. Revised Summary section. Removed references 4 and 5.
June 2021	Annual review
January 2022	Added Rinvoq as a preferred PsA product to chart (Appendix 4)
March 2022	Annual review. Added Skyrizi as a preferred PsA product to chart (Appendix 4)
April 2022	Added Rinvoq as a preferred UC product to chart (Appendix 4)
May 2022	Added Rinvoq as a preferred AS product to chart (Appendix 4)
June 2022	Annual review
September 2022	Annual review
December 2022	Annual review
June 2023	Annual review
March 2024	Annual editorial review. Revised FDA dosing language
June 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

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
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
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
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**
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 Stelara (SC)	Humira**

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

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