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Policy Number: 023.005

Title: Coverage Determination Policy for Simponi Aria (Golimumab) Intravenous

Regions: ☒ **Texas** ☐ **Florida** ☐ **Indiana** ☐ **New Jersey** ☒ **New Mexico**

Impacted Areas:

- ☒ Network Management/Provider Services
- ☐ Member services
- ☐ Quality Management
- ☐ Credentialing
- ☐ IT
- ☐ Administration
- ☐ Compliance/delegation
- ☒ Utilization Management
- ☐ Case management
- ☐ Disease management
- ☒ Claims
- ☐ Human resources
- ☐ Finance
- ☒ Pharmacy
- ☐ ALL

Available LCD/NCD/LCA: LCA: Self-Administered Drug Exclusion List (A53127)

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Coverage Policy Number: 023.005

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

Simponi Aria is proven and medically necessary for the treatment of ankylosing spondylitis, psoriatic arthritis and rheumatoid arthritis. This policy refers to golimumab injection for **intravenous infusion** only.

Simponi Aria for subcutaneous administration is excluded from Medicare Part B coverage because it is on the self-administered drug exclusion list and is therefore not a covered benefit. All request for subcutaneous Golimumab (Simponi) should be redirected to member's pharmacy benefits for coverage unless there is sufficient medical justification why patient cannot self-administer subcutaneous doses. (Local Coverage Article: Self-Administered Drug Exclusion List (A53127)).

PLEASE NOTE: All requests for IV Simponi Aria (Golimumab) Intravenous must include justification as to why IV route is medically necessary over the subcutaneous formulation of Golimumab. Medicare rules expect that if a patient is *clinically able* to self-administer a drug and there is no clear medical justification to do otherwise, then the patient must either self-administer that drug or self-pay for the alternative. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug. Medicare considers the following factors to be unrelated to medical decision making: 1. Patient convenience, 2. Patient co-pays and financial liability. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Initial/New Requests

WellMed Medical Management will cover **Simponi Aria (Golimumab)** Intravenous as medically necessary when **ALL** of the following are met for each indication:

Due to serious safety considerations outlined in the Black Box warning, ***documentation to support member has been screened for TB, HBV, active and / or serious infections should be included*** *for* ***ALL*** *indications.*

1. Ankylosing Spondylitis (AS)

A. Diagnosis of active ankylosing spondylitis

B. **ONE** of the following:

i. History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced

ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of ankylosing spondylitis [e.g., Cimzia (certolizumab), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

iii. Patient is currently on Simponi Aria

C. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis

D. Patient is NOT receiving Simponi Aria in combination with EITHER of the following:

i. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]

ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

2. Psoriatic Arthritis (PsA)

A. Diagnosis of active psoriatic arthritis

B. **ONE** of the following:

i. History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced

ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

iii. Patient is currently on Simponi Aria

C. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis

D. Patient is NOT receiving Simponi Aria in combination with ANY of the following:

i. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]

ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

3. Rheumatoid Arthritis (active)

A. Diagnosis of moderately to severely active rheumatoid arthritis

B. **ONE** of the following:

i. History of failure intolerance to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

iii. Patient is currently on Simponi Aria

C. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis

D. Patient is NOT receiving Simponi Aria in combination with EITHER of the following:

i. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]

ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Renewal/Continuation of Therapy Requests

WellMed Medical Management will cover **Simponi Aria (Golimumab)** Intravenous as medically necessary for continuation of therapy when **ALL** of the following are met for the above indications:

A. Physician documentation showing positive clinical response to therapy (e.g. reduction in member's signs and symptoms)

B. Member is receiving ongoing monitoring for presence of HBV, TB and active infections

C. The patient still meets indication specific criteria above with the exception of diagnosis of moderate-to-severe/active disease.

D. Simponi Aria is dosed according to US Food and Drug Administration (FDA) labeled dosing for the requested indication.

FDA Approved Dose and Indication

Indication	Approved Dosing
Ankylosing spondylitis, Active or Psoriatic arthritis, Active	• 2 mg/kg intravenous at week 0, 4, and then every 8 weeks thereafter
Rheumatoid arthritis (Moderate to severe), Active	• 2 mg/kg intravenous at week 0, 4, and then every 8 weeks thereafter • Give in combination with methotrexate except when clinical contraindicated

General Background

Simponi Aria is a monoclonal antibody that binds to tumor necrosis factor (TNF), thereby inhibiting TNF alfa activity by blocking the binding of TNF alfa to its receptor. Elevated TNF alfa level may be associated with ankylosing spondylitis (AS), psoriatic arthritis (PsA), plaque psoriasis, and rheumatoid arthritis (RA).

Simponi Aria is indicated for the treatment of ankylosing spondylitis, psoriatic arthritis and rheumatoid arthritis.

Warnings

Serious infections such as bacterial sepsis, invasive fungal, opportunistic infection, and tuberculosis have been reported in patients treated with Simponi Aria. Black box warning for Simponi Aria states an increase risks to patients with serious infections, which may lead to hospitalization or death. It is recommended to discontinue Simponi Aria if patients develop serious infection. For patients with positive latent TB, it is advised to start treatment for TB prior to starting Simponi Aria.

Clinical Evidence

Weinblatt ME et al conducted randomized, multicenter, double-blind, placebo-controlled GO-FURTHER phase 3 trial. The efficacy of intravenous golimumab was evaluated in patients with active rheumatoid arthritis (RA) receiving Methotrexate. The study randomized 592 patients in 92 sites worldwide. Patients were 18 – 83 years old and mostly Caucasian (80.4 %). The primary endpoint was the proportion of patients with an American College of Rheumatology 20% (ACR20) response at week 14. Patients were randomized (2:1) to receive intravenous golimumab 2 mg/kg, or placebo infusions at weeks 0 and 4 and every (q) 8 weeks in addition to methotrexate. Significant proportion of patients in golimumab and methotrexate achieved ACR20 response compared to patients in placebo and methotrexate (59% vs 25% respectively, P < 0.001). The study concluded that the addition of golimumab significantly improved signs and symptoms of RA in patients on methotrexate.

Braun J et al. evaluated golimumab effect on MRI-detected spinal inflammation in ankylosing spondylitis (AS) patients. The trial was a randomized, placebo- controlled GO-RAISE study. Patients were randomized to subcutaneous injections of golimumab 50 mg (n=138), golimumab 100 mg (n=140) or placebo (n=78), every 4 weeks. The primary goal was to compare ankylosing spondylitis spine MRI-activity (ASspiMRI-a) scores at baseline, weeks 14 and 104 in all subjects. Two blinded readers independently evaluated MRI spinal inflammation using ankylosing spondylitis (AS) spine. At baseline, ASspiMRI-a scores was 7.8 for patients on golimumab 50 mg; 3.5 for patients on 100 mg golimumab and 6.8 for placebo patients. Median decreases in activity scores from baseline to week 14 were −3.5 for 50 mg (p=0.047 vs placebo), −1.5 for 100 mg (p=0.14 vs placebo) and −0.5 for placebo. Significant improvements were reported in ASspiMRI-a score after adjusting for baseline imbalance with both 50 mg (p=0.011) and 100 mg (p=0.002) versus placebo. The benefits were maintained at week 104. The study concluded that golimumab significantly reduced MRI-detected spinal inflammation of AS.

Kavanaugh A et al conducted a phase III, randomized, double-blind, placebo-controlled trial. The safety and efficacy of intravenous (IV) golimumab treatment in active psoriatic arthritis (PsA) patients was evaluated. A total of 817 patients were screened, and 480 patients were randomized to golimumab intravenous treatment 2 mg/kg (n = 241) or placebo (n = 239) at weeks 0, 4, and every 8 weeks. The study was conducted at 90 sites in 11 countries including the US. The primary end point was the number of patients who meet the American College of Rheumatology 20% improvement criteria (ACR20) at week 14. There were other secondary end points measured during the study. Approximately, 75.1% of patients in the golimumab group achieved the primary end point goal (ACR20 response) compared with 21.8% in the placebo group ($P < 0.001$). At week 24, 46.3% of patients in the golimumab group reported at least one adverse effect vs 40.6% of patients in the placebo group. Infections were the most reported type of adverse effects among patients who received golimumab; however, there were no cases of opportunistic infections or active TB through week 24. The study concluded that patients in the IV golimumab 2 mg/kg achieved significantly greater improvements in the signs and symptoms of PsA and less radiographic progression through week 24.

HCPCS Code

HCPCS Code	Description
J1602	Simponi Aria (Intravenous Golimumab)

Dosage Form, Strength, and Route of Administration
50 mg/4 mL (12.5 mg/mL) solution in a single-dose vial, administered IV

Acronyms

AS = Ankylosing spondylitis

PsA = Psoriatic arthritis

RA = Rheumatoid arthritis

DMARDs = Disease Modifying Antirheumatic Drugs

TNF = Tumor Necrosis Factor

NCD = National Coverage Determination

LCD = Local Coverage Determinations

ACR20 = American College of Rheumatology 20%

ASspiMRI-a = Ankylosing Spondylitis spine MRI-activity

FDA = Food and Drug Administration

HBV = Hepatitis B virus

TB = Tuberculosis

NSAIDs = Non-steroidal anti-inflammatory drugs

MTX = methotrexate

References

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