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Golimumab

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Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

Coverage

NOTE 1: This medical policy does NOT address oncologic indications. This medical policy IS NOT TO BE USED for oncologic indications. Refer to RX502.061 Oncology Medications for oncologic indications.

NOTE 2: Golimumab (Simponi®) is self-administered. Please refer to applicable pharmacy benefit plan.

Golimumab (Simponi Aria®)

Golimumab (Simponi Aria®) **may be considered medically necessary** for the following indications:

- Adult individuals with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX);
- Active psoriatic arthritis (PsA) in individuals 2 years of age and older;
- Adult individuals with active ankylosing spondylitis (AS); or
- Active polyarticular juvenile idiopathic arthritis (pJIA) in individuals 2 years of age and older.

NOTE 3: Golimumab (Simponi Aria) may NOT be used concomitantly with interleukin-1 antagonists or tumor necrosis factor (TNF) antagonists.

Other Indications

Golimumab (Simponi Aria®) **is considered experimental, investigational, and/or unproven** for all other non-Food and Drug Administration approved indications.

Policy Guidelines

None.

Description

Golimumab is a human monoclonal antibody specific for human tumor necrosis factor alpha (TNFα). It binds to both the soluble and transmembrane bioactive forms of human TNFα. Elevated TNFα levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). In clinical trials, decreases in C-reactive protein (CRP), interleukin (IL)-6, matrix metalloproteinase-3 (MMP-3), intercellular adhesion

molecule (ICAM)-1, and vascular endothelial growth factor (VEGF) were observed following Simponi administration in patients with RA, PsA, and AS.

Rheumatoid Arthritis
Rheumatoid arthritis (RA) is an autoimmune and inflammatory disease in which the immune system attacks healthy cells by mistake, causing inflammation or painful swelling in affected parts of the body. RA mainly attacks the joints in the hands, wrists and knees, and usually attacks many joints at the same time. The lining of the joint becomes inflamed, causing damage to joint tissue, which in turn causes long-lasting or chronic pain, unsteadiness, and deformity of the affected joints. RA can also affect other tissues in the body and cause problems in organs such as the lungs, heart, and eyes. (2)

Psoriatic Arthritis
Psoriatic arthritis is a condition involving joint inflammation (arthritis) that usually occurs in conjunction with psoriasis, a skin disorder characterized by patches of red, irritated skin that are often covered by flaky white scales. Psoriasis may cause changes to fingernails and toenails, causing pitting, ridges, crumbling of the nail or separation of the nail from the nail bed. PsA causes stiff, painful joints with redness, heat and swelling in the surrounding tissues. Swelling and redness may result in a sausage-like appearance of the fingers or toes when the hands or feet are affected. Psoriasis appears before joint problems develop in most people. Both conditions may occur at any age; and in a small number of cases, PsA develops without any noticeable skin changes. (3)

Ankylosing Spondylitis
Ankylosing spondylitis (AS) is a form of arthritis affecting the spine. It often involves redness, heat, swelling and pain in the spine or in the joint where the bottom of the spine (sacrum) joins the pelvic bone (ilium). It can also affect the shoulders, ribs, hips, knees and feet, as well as areas where the tendons and ligaments attach to the bones. Sometimes it can affect the eyes, bowel and very rarely, the heart and lungs. AS is more than twice as likely to affect men as it is women. (4)

Polyarticular Juvenile Idiopathic Arthritis
Juvenile idiopathic arthritis (JIA) is characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other identifiable cause. Polyarticular JIA (pJIA) is defined by the presence of more than four affected joints in the first six months of disease. Children with pJIA tend to have a more refractory course of disease compared to those with fewer affected joints, putting them at an increased risk for joint damage and resulting in poorer functional outcomes and decreased quality of life. (5)

Regulatory Status
The U.S. Food and Drug Administration (FDA) approved Simponi Aria® to treat adults with moderately to severely active RA in 2013. In 2017, the FDA granted approval for the treatment of adults with PsA or active AS. Additional FDA approval was granted in 2020 for pediatric indications, to include both active pJIA and PsA in patients 2 years of age and older. (6)

Rationale

This medical policy is based on the U.S. Food and Drug Administration (FDA) labeled indications for golimumab (Simponi Aria®).

Rheumatoid Arthritis (1)
The efficacy and safety of Simponi Aria® were evaluated in one multicenter, randomized, double-blind, controlled trial (Trial RA, NCT00973479) in 592 patients ≥ 18 years of age with moderately to severely active rheumatoid arthritis (RA) despite concurrent methotrexate (MTX) therapy and had not previously been treated with a biologic TNF-blocker. Patients were diagnosed according to the American College of Rheumatology (ACR) criteria, at least 3 months prior to administration of study agent and were required to have at least 6 swollen and 6 tender joints. Patients were randomized to receive either Simponi Aria 2 mg/kg (N=395) or placebo (N=197) over a 30-minute intravenous infusion at Weeks 0, 4 and every 8 weeks thereafter in addition to their weekly maintenance MTX dose (15-25 mg). All patients receiving placebo + MTX received Simponi Aria + MTX after Week 24, but the trial remained blinded until all patients had completed 108 weeks of treatment. Efficacy data were collected and analyzed through Week 52. Patients were allowed to continue stable doses of concomitant low dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day) and/or nonsteroidal anti-inflammatory drugs (NSAIDs). The use of other disease-modifying anti-rheumatic drugs (DMARDs) including cytotoxic agents or other biologics was prohibited.

The primary endpoint in Trial RA was the percentage of patients achieving an ACR 20 response at Week 14. In Trial RA, the majority of subjects were women (82%) and were Caucasian (80%) with a median age of 52 years and a median weight of 70 kg. Median disease duration was 4.7 years, and 50% of the patients used at least one DMARD other than MTX in the past. At baseline, 81% of patients received concomitant NSAIDs and 81% of patients received low-dose corticosteroids (equivalent to ≤ 10 mg of prednisone a day). The median baseline Disease Activity Score-28 for Rheumatoid Arthritis with CRP (DAS28-CRP) was 5.9 and the median van der Heijde-Sharp (vdH-S) score at baseline was 28.5.

Clinical Response
A greater percentage of patients treated with the combination of Simponi Aria + MTX achieved ACR 20 at Week 14 and ACR 50 at Week 24 versus patients treated with the placebo + MTX. The improvement in all components of the ACR response criteria for the Simponi Aria + MTX group was greater compared to the placebo + MTX group in Trial RA. At Week 14, a greater proportion of patients treated with Simponi Aria + MTX achieved a low level of disease activity as measured by a DAS28-CRP less than 2.6 compared with the placebo + MTX group (15% compared to 5%; 95% CI for difference [6.3%, 15.5%]).

Radiographic Response

In Trial RA, structural joint damage was assessed radiographically and expressed as a change in vdH-S and its components, the erosion score and Joint Space Narrowing (JSN) score, at Week 24 compared to baseline. The Simponi Aria + MTX treatment group inhibited the progression of structural damage compared with placebo + MTX, as assessed by total vdH-S score.

At Week 24, a greater proportion of patients in the Simponi Aria + MTX group (71%) had no progression of structural damage (change in the total vdH-S score ≤ 0), compared to 57% of patients in the placebo + MTX group. At Week 52, the mean change from baseline in total vdH-S score was 1.2 in patients originally randomized to placebo + MTX who crossed over to Simponi Aria + MTX at Week 16 or Week 24, and 0.1 in patients originally randomized to Simponi Aria + MTX who remained on active treatment.

Physical Function Response in Patients with RA

Physical function was assessed by the disability index of the Health Assessment Questionnaire (HAQ-DI). At Week 14, the Simponi Aria + MTX group showed greater mean improvement in the HAQ-DI compared with placebo + MTX (0.5 compared to 0.2; 95% CI for difference [0.2, 0.4]).

Other Health-Related Outcomes

General health status was assessed by the 36-item Short Form Health Survey (SF-36). In Trial RA, patients receiving Simponi Aria + MTX demonstrated greater improvement from baseline compared with placebo + MTX in physical component summary (PCS), mental component summary (MCS) scores and in all 8 domains of the SF-36.

Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F) in Trial RA. Treatment with Simponi Aria resulted in improvement in fatigue as measured by the FACIT-F.

Psoriatic Arthritis (1)

The efficacy and safety of Simponi Aria were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 480 patients ≥ 18 years of age with active psoriatic arthritis (PsA) despite NSAID or DMARD therapy (Trial PsA, NCT02181673). Previous treatment with a biologic was not allowed. Patients in this trial had a diagnosis of PsA for at least six months and had symptoms of active disease [≥5 swollen joints and ≥5 tender joints and a CRP level of ≥ 0.6 mg/dL]. Patients were randomized to either receive Simponi Aria 2 mg/kg (N=241) or placebo (N=239) as a 30-minute intravenous infusion at Weeks 0, 4, 12 and 20. All patients on placebo received Simponi Aria at Week 24, Week 28 and every 8 weeks thereafter through Week 52. Patients in the Simponi Aria treatment group continued to receive Simponi Aria infusions at Week 28 and every 8 weeks through Week 52.

Patients were allowed to continue stable doses of MTX, NSAIDs, and low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day) during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an ACR 20 response at Week 14.

Patients with each subtype of PsA were enrolled, including polyarticular arthritis with absence of rheumatoid nodules (44%), asymmetric peripheral arthritis (19%), distal interphalangeal joint involvement (8.1%), spondylitis with peripheral arthritis (25%), and arthritis mutilans (4.8%). The median duration of PsA disease was 3.5 years, 86% of patients had previously used MTX, and 35% of patients received at least one other DMARD in the past. At baseline, 76% and 54% of the patients had enthesitis and dactylitis, respectively. The median total modified vdH-S score at baseline was 15.5. During the trial, concomitant medications used included MTX (70%), oral corticosteroids (28%), and NSAIDs (71%).

Clinical Response

In Trial PsA, Simponi Aria treatment, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ACR 20 response at Week 14. Similar ACR 20 responses at Week 24 were observed in patients with different PsA subtypes. ACR 20 responses observed in the Simponi Aria-treated groups were similar in patients who were or were not receiving concomitant MTX.

Patients with enthesitis at baseline were evaluated for mean improvement using the Leeds Enthesitis Index (LEI) on a scale of 0-6. Simponi Aria-treated patients showed a significantly greater improvement in enthesitis, with a mean reduction of 1.8 as compared with a mean reduction in placebo-treated patients of 0.8 at Week 14. Patients with dactylitis at baseline were evaluated for mean improvement on a scale of 0-60. Simponi Aria-treated patients showed a significantly greater improvement, with a mean reduction of 7.8 compared with a mean reduction of 2.8 in placebo-treated patients at Week 14.

Radiographic Response

In Trial PsA, structural joint damage was assessed radiographically and expressed as a change from baseline at Week 24 in total modified vdH-S score and its components, the erosion score and JSN score. Simponi Aria inhibited the progression of structural damage compared with placebo, as assessed by total modified vdH-S score. At Week 24, a greater proportion of patients in the Simponi Aria group (72%) had no progression of structural damage (change in the total modified vdH-S score ≤ 0), compared to 43% of patients in the placebo group.

Physical Function and Responses

Improvement in physical function as assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved clinically meaningful improvement of ≥ 0.3 in HAQ-DI score from baseline was greater in the Simponi Aria-treated group compared to placebo at Week 14 (69% compared to 32%).

Other Health Related Outcomes

General health status was assessed by the 36-item Short Form Health Survey (SF-36). In Trial PsA, patients receiving Simponi Aria demonstrated greater improvement from baseline compared with placebo in physical component summary, mental component summary scores and in all 8 domains of the SF-36.

Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F) in Trial PsA. Treatment with Simponi Aria resulted in improvement in fatigue as measured by the FACIT-F.

Treatment of Pediatric Patients

The efficacy of Simponi Aria in pediatric patients with PsA is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in adult PsA patients in Trial PsA.

Ankylosing Spondylitis (1)

The efficacy and safety of Simponi Aria were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial (Trial AS, NCT02186873) in 208 patients ≥ 18 years of age with active ankylosing spondylitis (AS) and inadequate response or intolerance to NSAIDs. Patients had a diagnosis of definite AS for at least 3 months according to modified New York criteria. Patients had symptoms of active disease [Bath AS Disease Activity Index (BASDAI) ≥ 4, visual analog scale (VAS) for total back pain of ≥ 4, on scales of 0 to 10 cm (0 to 100 mm), and a high-sensitivity C-reactive protein (hsCRP) level of ≥ 0.3 mg/dL (3 mg/L)].

Patients were randomized to receive either Simponi Aria 2 mg/kg (N=105) or placebo (N=103) as a 30-minute intravenous infusion at Weeks 0, 4 and 12. All patients on placebo received Simponi Aria at Week 16, Week 20 and every 8 weeks thereafter through Week 52. Patients in the Simponi Aria treatment group continued to receive Simponi Aria infusions at Week 20 and every 8 weeks through Week 52. Patients were allowed to continue stable doses of concomitant MTX, sulfasalazine (SSZ), hydroxychloroquine (HCQ), low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day), and/or NSAIDs during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited.

The primary endpoint was the percentage of patients achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response at Week 16. In Trial AS, the median duration of AS disease was 2.8 years, median duration of inflammatory back pain was 8 years, 90% were HLA-B27 positive, 8.2% had prior joint surgery or procedure, 5.8% had complete ankylosis of the spine, 14% had received prior therapy with one biologic TNF blocker (other than golimumab) and discontinued for reasons other than lack of efficacy within the first 16 weeks of treatment (primary failure), and 76% received at least one DMARD in the past. During the trial, the use of concomitant medications was NSAIDs (88%), SSZ (38%), corticosteroids (26%), MTX (18%), and HCQ (0.5%).

Clinical Response

In Trial AS, Simponi Aria treatment, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ASAS 20 response at Week 16. At Week 16, a greater percentage of patients treated with Simponi Aria achieved a low level of disease activity (<2 [on a scale of 0 to 10 cm] in all four ASAS domains) compared with patients treated with placebo (16.2% vs. 3.9%).

Other Health-Related Outcomes

General health status was assessed by the 36-item Short Form Health Survey (SF-36). In Trial AS, patients receiving Simponi Aria demonstrated greater improvement from baseline compared with placebo in physical component summary and mental component summary scores and in all 8 domains of the SF-36. Simponi Aria-treated patients showed significant improvement compared with placebo-treated patients in health-related quality of life as assessed by the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL).

Polyarticular Juvenile Idiopathic Arthritis (1)

The efficacy of Simponi Aria in pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA) is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in RA patients. Efficacy of Simponi Aria was also assessed in a multicenter, open-label, single-arm study in 127 children (2 to < 18 years of age) with JIA with active polyarthritis despite treatment with MTX for at least 2 months (Trial pJIA, NCT02277444). The polyarticular JIA patient subtypes at study entry included: rheumatoid factor negative (43%), rheumatoid factor positive (35%), enthesitis-related arthritis (9%), oligoarticular extended (6%), juvenile PsA (4%), and systemic JIA without systemic manifestations (3%). All patients received Simponi Aria 80 mg/m^2 as an intravenous infusion at Week 0, 4, and every 8 weeks through Week 52. Patients continued stable doses of MTX weekly through Week 28; after Week 28, changes in MTX dose were permitted. Efficacy was assessed as supportive endpoints through Week 52. The efficacy was generally consistent with responses in patients with RA.

Summary of Evidence

Based on the clinical studies provided to the U.S. Food and Drug Administration, golimumab (Simponi Aria®) may be considered medically necessary for the treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate, and active ankylosing spondylitis. Additionally, golimumab (Simponi Aria®) may be considered medically necessary for active psoriatic arthritis (PsA) and active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	J1602

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

U.S. Food and Drug Administration:

1. U.S. Food and Drug Administration, Drugs@FDA. Highlights of Prescribing Information: Simponi Aria (revised February 2021). Available at: <https://www.accessdata.fda.gov> (accessed June 24, 2025).

Other:

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4. Wenker KJ, Quint JM. Ankylosing Spondylitis. In: StatPearls. Treasure Island (FL): StatPearls Publishing; June 20, 2023.
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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
08/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Revised NOTEs 1 and 3; and 2) Added “non-Food and Drug Administration approved” to experimental, investigational, and/or unproven statement. No new references added.
03/15/2025	Document updated with literature review. The following change was made to Coverage: 1) Added “NOTE 1: This medical policy does NOT address oncologic indications. This medical policy IS NOT TO BE USED for oncologic indications.” Reference 5 added.
03/15/2024	Document updated with literature review. Coverage unchanged. References 2 and 3 added, others updated, some removed.

03/15/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. The following change was made to Coverage: Added NOTE 2: Golimumab (Simponi Aria) shall not be used concurrently with other biologics used to treat the indications above. Please refer to the Description Section for a list of biological disease-modifying antirheumatic drugs (DMARDs). References revised; none added.
11/01/2021	Reviewed. No changes.
01/15/2021	Document updated with literature review. The following changes were made to Coverage: 1) Expanded age criterion for active psoriatic arthritis to include patients 2 years of age and older; and 2) Added indication for active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Added/updated the following references: 4-6.
10/01/2020	New medical document originating from RX501.051. NOTE: Golimumab (Simponi®) is self-administered. Please refer to the applicable pharmacy benefit plan. Golimumab (Simponi Aria®) may be considered medically necessary for the treatment of adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate (MTX); active psoriatic arthritis or active ankylosing spondylitis. Simponi Aria is considered experimental, investigational and/or unproven for all other indications.