

golimumab (Simponi Aria)

Commercial Medical Benefit Drug Policy

Place of Service

Home Health Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

Mechanism of Action: monoclonal antibody tumor necrosis factor (TNF) blocking agent.

HCPCS:

J1602:Injection, golimumab, 1 mg, for intravenous use

How Supplied:

50 mg/4 mL solution (single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Ankylosing Spondylitis (AS)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- Psoriatic Arthritis (PsA)
- Rheumatoid Arthritis (RA)

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Simponi Aria given by intravenous injection is managed under the Medical Benefit.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is receiving their first two doses of Simponi Aria or is being re-initiated on Simponi Aria after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Simponi Aria based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Simponi Aria based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Ankylosing Spondylitis (AS)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with a rheumatologist
2. Meets ONE of the following:
 - a. Inadequate response with a trial of any two-prescription strength NSAIDs
 - b. Intolerable GI adverse events after a trial of a prescription strength NSAID in combination with a PPI
 - c. Unable to take NSAIDs due to history of GI bleed
3. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)
4. Inadequate response or intolerable side effect with two BSC-preferred agents (adalimumab-aacf, Cosentyx SC, Enbrel, infliximab (Inflectra or Avsola), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Reauthorization:

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:

Up to 2 mg/kg given intravenously at weeks 0 and 4, then every 8 weeks

golimumab (Simponi Aria)

Coverage Period:

one year

ICD-10:

M45.0-M45.9

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response or intolerance to a disease modifying anti-rheumatic drugs (DMARD) or documented medical reason why methotrexate cannot be used
3. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors)
4. Inadequate response or intolerable side effect with two of the following BSC-preferred agents (adalimumab-aacf, Enbrel, Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Reauthorization:

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors)

Covered Doses:

Up to 80 mg/m² given intravenously at weeks 0 and 4, and every 8 weeks thereafter

Coverage Period:

one year

ICD-10:

M08.00-M08.40

Psoriatic Arthritis (PsA)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerance, or contraindication to one or more disease modifying anti-rheumatic drugs (DMARDs), or has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used
3. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)
4. Inadequate response, intolerable side effect, with two BSC-preferred agents (adalimumab-aacf, Cosentyx SC, Enbrel, infliximab (Avsola or Inflectra), Otezla, Rinvoq, Skyrizi SC, Yesintek SC, Tremfya SC, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Reauthorization:

1. Patient is responding to therapy

2. **Effective 2/1/2026 and after:** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:

Up to 2 mg/kg given intravenously at weeks 0 and 4, then every 8 weeks

Coverage Period:

one year

ICD-10:

L40.50-L40.59

Rheumatoid Arthritis (RA)

Meets medical necessity if all the following are met:

Initial:

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to a DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, and sulfasalazine)
3. Not used in combination with another targeted immunomodulator (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)
4. Inadequate response or intolerable side effect with two BSC-preferred agents (adalimumab-aacf, Enbrel, infliximab (Avsola or Inflectra), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents

Reauthorization:

1. Patient is responding to therapy
2. **Effective 2/1/2026 and after:** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:

Up to 2 mg/kg given intravenously at weeks 0 and 4, then every 8 weeks

Coverage Period:

one year

ICD-10:

(X=0-9) M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939.
4. MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
5. Simponi Aria (golimumab) [Prescribing information]. Janssen Biotech Inc., Horsham, PA. April 2025.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum* 2019; 71:5-32.

7. Ward, MM, Deodhar A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*, 2019;71(10):1599-1613.
8. Ringold S MD, MS, Angeles-Han S MD, MSc, Beukelman T MD, MSCE, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacrolitis, and Enthesitis. *Arthritis Rheum* 2019 Jun;71(6):846-863.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Ankylosing Spondylitis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis: Added reauthorization criteria
- Rheumatoid Arthritis: Clarified prerequisite requirement to include DMARDs for rheumatoid arthritis and added reauthorization criteria

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*