golimumab (Simponi Aria®) intravenous

Medicare Advantage Medical Policy #MA-145
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Health Plan may consider the use of intravenous (IV) golimumab (Simponi Aria®)‡ for the treatment of rheumatoid arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis; AND
- Simponi Aria is used in combination with methotrexate unless there is a contraindication to taking methotrexate or a history of methotrexate intolerance; AND
- Patient has failed treatment with one or more traditional disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira®, biosimilars)‡ OR other drugs such as apremilast (Otezla®)‡ or tofacitinib (Xeljanz/XR®)‡; AND
- Patient has a negative tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Health Plan may consider the use of IV golimumab (Simponi Aria) for the treatment of psoriatic arthritis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 2 years of age or older; AND
- Patient has active psoriatic arthritis; AND

- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Ankylosing Spondylitis

Based on review of available data, the Health Plan may consider the use of IV golimumab (Simponi Aria) for the treatment of ankylosing spondylitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active ankylosing spondylitis; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs) unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
- Simponi Aria is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Polyarticular Juvenile Idiopathic Arthritis

Based on review of available data, the Health Plan may consider the use of IV golimumab (Simponi Aria) for the treatment of polyarticular juvenile idiopathic arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of IV golimumab (Simponi Aria) will be considered when all of the following criteria are met:

- Patient is 2 years of age or older; AND
- Patient has active polyarticular juvenile idiopathic arthritis; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Health Plan considers the use of IV golimumab (Simponi Aria) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For rheumatoid arthritis and psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs
- For polyarticular juvenile idiopathic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of IV golimumab (Simponi Aria) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Health Plan considers the use of IV golimumab (Simponi Aria) for indications other than those listed above to be **investigational.***

Background/Overview

Simponi Aria is approved for use in patients with rheumatoid arthritis, psoriatic arthritis (2 years and older), polyarticular juvenile idiopathic arthritis (2 years and older), and ankylosing spondylitis. TNF is a naturally occurring cytokine that is involved with the inflammatory and immune responses. Excessive activation of immune effector cells and overproduction of TNF can cause severe inflammation and tissue damage. Inhibition of TNF activity in certain inflammatory diseases may alleviate symptoms and prevent disease progression. Simponi Aria is given at 2 mg/kg at weeks 0 and 4, then every 8 weeks in adult patients. In pediatric patients with polyarticular juvenile idiopathic arthritis or psoriatic arthritis, the dose is 80 mg/m^2 at weeks 0 and 4, then every 8 weeks thereafter.

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Psoriatic Arthritis
Psoriatic Arthritis is an arthritis that is often associated with psoriasis of the skin. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Ankylosing Spondylitis
Ankylosing spondylitis is a chronic inflammatory disease that affects the joints between the vertebrae of the spine, and the joints between the spine and the pelvis. It eventually causes the affected vertebrae to fuse or grow together. Nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen, are used to reduce inflammation and pain associated with the condition. Corticosteroid therapy or medications to suppress the immune system may be prescribed to control various symptoms.

Polyarticular Juvenile Idiopathic Arthritis
Polyarticular juvenile idiopathic arthritis includes the inflammation of joints and presence of arthritis in children. Polyarticular juvenile idiopathic arthritis typically occurs in a symmetrical manner with knees, wrists, and ankles most frequently affected. However certain subgroups of children do have predominantly asymmetrical involvement. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Traditional Disease-Modifying Anti-Rheumatic Drugs
Traditional DMARDS are typically used to treat various inflammatory conditions. These drugs slow the disease process by modifying the immune system:

- methotrexate
- cyclosporine
- sulfasalazine
- mercaptopurine
- gold compounds

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Simponi Aria is FDA approved for the treatment of adults with moderate to severe rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Simponi Aria is also approved for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis or psoriatic arthritis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Simponi Aria for the treatment of rheumatoid arthritis was evaluated in one multi-center, randomized, double-blind, placebo-controlled trial in 592 adult patients. Patients were randomized to receive either Simponi Aria 2 mg/kg or placebo at weeks 0, 4, and every 8 weeks in addition to methotrexate. A greater percentage of patients treated with Simponi Aria plus methotrexate achieved ACR20 at week 14 and ACR 50 at week 24 versus patients treated with placebo. Simponi Aria was evaluated in active psoriatic arthritis in 480 patients. The primary endpoint was the percentage of patients achieving an ACR20 response at week 14. At week 14, 22% of the subjects in the placebo group achieved an ACR20 while 75% in the Simponi Aria group achieved an ACR20 at week 14. The efficacy of Simponi Aria in pediatric patients with psoriatic arthritis is based on the pharmacokinetic exposure and extrapolation of the established efficacy of Simponi Aria in adult psoriatic arthritis patients. The efficacy and safety of Simponi Aria in ankylosing spondylitis was evaluated in 208 patients. The primary endpoint was the percentage of patients achieving an ASAS20 response at week 16. At week 16, 26% of placebo patients achieved an ASAS20 vs. 73% in the Simponi Aria group. The efficacy and safety of Simponi Aria in polyarticular juvenile idiopathic arthritis is based on pharmacokinetic exposure and extrapolation of the established safety and efficacy of Simponi Aria in patients with rheumatoid arthritis. Efficacy was also assessed in pediatric patients 2 to 18 years of age. The efficacy was generally consistent with responses in patients with rheumatoid arthritis.

References

1. Simponi Aria [package insert]. Janssen Biotech, Inc. Horsham, Pennsylvania. Updated April 2025.
2. Keystone EC, Genovese MC, Klareskog L, Hsia EC, Hall ST, Miranda PC, Pazdur J, Bae SC, Palmer W, Zrubek J, Wiekowski M, Visvanathan S, Wu Z, Rahman MU; GO-FORWARD Study. Golimumab, a human antibody to tumour [sic] necrosis factor {alpha} given by monthly subcutaneous injections, in active rheumatoid arthritis despite methotrexate therapy: the GO-FORWARD Study. Ann Rheum Dis. 2009 Jun; 68(6):789-96. Epub 2008 Dec 9.
3. Zhou H, Jang H, Fleischmann RM, Bouman-Thio E, Xu Z, Marini JC, Pendley C, Jiao Q, Shankar G, Marciniak SJ, Cohen SB, Rahman MU, Baker D, Mascelli MA, Davis HM, Everitt DE. Pharmacokinetics and safety of golimumab, a fully human anti-TNF-alpha monoclonal antibody, in subjects with rheumatoid arthritis. J Clin Pharmacol. 2007 Mar; 47(3):383-96.

Policy History

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09/16/2025 UM Committee review and approval. New policy.

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Next Scheduled Review Date: 09/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J1602
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.