



POLICIES AND PROCEDURE MANUAL

Policy: MBP 112.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Simponi Aria (golimumab)

Applicable line of business:

| | | | |
|------------|---|----------|---|
| Commercial | X | Medicaid | |
| Medicare | X | ACA | X |
| CHIP | X | | |

I. Policy:

Simponi Aria (golimumab)

II. Purpose/Objective:

To provide a policy of coverage regarding Simponi Aria (golimumab)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION:

Simponi Aria (golimumab) is a human monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNF α . This interaction prevents the binding of TNF α to its receptors, thereby inhibiting the biological activity of TNF α (a cytokine protein). Elevated TNF α levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. TNF α is an important mediator of the articular inflammation that is characteristic of these diseases.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Simponi Aria (golimumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met per indication:

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of a preferred adalimumab product*, Rinvoq*, OR Xeljanz* therapy.

Psoriatic Arthritis

- Requesting provider must be a rheumatologist or dermatologist **AND**
 - Medical record documentation of age ≥ 2 years **AND**
 - Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
 - Documentation of active psoriatic lesions OR documentation of a history of psoriasis
- AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
 - For patients 18 years of age and older, medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** a preferred adalimumab product*.

Ankylosing Spondylitis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** a preferred adalimumab product*.

Polyarticular juvenile idiopathic arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 4 month trial of a preferred adalimumab product*.

(*requires prior authorization)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of disease at six (6) months of Simponi Aria therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of disease while on Simponi Aria therapy.

Simponi Aria (golimumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met per indication:

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent

Psoriatic Arthritis

- Requesting provider must be a rheumatologist or dermatologist **AND**
- Medical record documentation of age ≥ 2 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
 - Documentation of active psoriatic lesions OR documentation of a history of psoriasis**AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent

Ankylosing Spondylitis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent

Polyarticular juvenile idiopathic arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of disease at six (6) months of Simponi Aria therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of disease while on Simponi Aria therapy.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Simponi Aria [prescribing information]. Horsham, PA: Janssen Biotech Inc; February 2021.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. American College of Rheumatology (ACR). Arthritis Care & Research; 2021 July; 73(7):924-939 [cited 2023 Dec 27]. Available from: <https://rheumatology.org/rheumatoid-arthritis-guideline>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 07/18/14

Revised: 09/16/14, 12/30/14 (updated formulary alternatives criteria), 9/15/15 (removed joint counts), 3/20/18 (PsA and AS indication), 4/24/18 (per DHS, grandfather), 9/18/18 (RA form alt), 1/21/20 (RA form alt), 3/16/21 (PJIA, PsA age), 3/13/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added), 2/19/24 (description updated), 2/11/25 (updated Humira [per 11/2025 P&T], LOB table, taglines, removed Medicaid business segment)

Reviewed: 9/14/16, 7/31/17, 1/19/21, 3/14/22

MA UM Committee approval: 12/31/23, 12/31/24