SmartHealth Ascension

Golimumab

(Simponi Aria®) J1602 (1mg)

Covered with prior authorization

Simponi Aria® (golimumab) may be authorized when the following criteria are met:

Ankylosing spondylitis

- Individual meets **ALL** of the following criteria**:**
  - Individual has a documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for **ONE** non-steroidal, anti-inflammatory drug (NSAIDs).
    - ***Note:*** *An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try an NSAID.*
  - The medication is prescribed by or in consultation with a rheumatologist or prescriber who specializes in Ankylosing Spondylitis.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

- Individual meets **ALL** of the following criteria**:**
  - Individual is 2 years of age and older
  - The medication is prescribed by or in consultation with a rheumatologist or a prescriber who specializes in PJIA

Psoriatic arthritis

- Individual meets **ALL** of the following criteria**:**
  - Individual has documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for **ONE** conventional disease-modifying anti-rheumatic drug (DMARD) (for example, methotrexate, leflunomide, sulfasalazine).
    - ***Note:*** *An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try a conventional DMARD.*
  - The medication is prescribed by or in consultation with a rheumatologist, dermatologist, or a prescriber who specializes in psoriatic arthritis.

Rheumatoid arthritis

- Individual meets **ALL** of the following criteria
  - Individual has documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for **ONE** conventional disease-modifying anti-rheumatic drug (DMARD) (for example, methotrexate, leflunomide, sulfasalazine).

- If NO contraindication or intolerance to methotrexate, must be used in combination with methotrexate (MTX).
  - ***Note:*** *An exception to this requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and try a DMARD.*
- The medication is prescribed by or in consultation with a rheumatologist or a prescriber who specializes in rheumatoid arthritis or a prescriber who specializes in rheumatoid arthritis.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Concomitant use with any other biologic including all non-tumor necrosis factor (non-TNF) biologics, anti-TNF biologics, or oral immunomodulatory agents (for example, Otezla or Xeljanz/ Xeljanz XR).
- Behcet's disease.
- Granulomatosis with polyangiitis.
- Pyoderma gangrenosum.
- Ulcerative colitis.

Initial authorization is up to 12 months.

Reauthorization approval duration is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Simponi Aria® (golimumab) is a tumor necrosis factor (TNF) blocker indicated for the treatment of: adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate (MTX), active Psoriatic Arthritis (PsA) in patients 2 years of age or older, active Ankylosing Spondylitis (AS), and active Polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older.

FDA Recommended Dosing
Dosage in Adults with Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis

The Simponi Aria® dosage regimen is 2 mg per kg given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter. Follow the dilution and administration instructions for Simponi Aria®.
For patients with rheumatoid arthritis (RA), Simponi Aria® should be given in combination with methotrexate. The efficacy and safety of switching between intravenous and subcutaneous formulations and routes of administration have not been established.

Dosage in Pediatric Patients with Polyarticular Juvenile Idiopathic Arthritis and Psoriatic Arthritis
The Simponi Aria® dosage regimen, based on body surface area (BSA), is 80 mg/m 2 given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter. Follow the dilution and administration instructions for Simponi Aria®.

References:

1. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 treatment recommendations for psoriatic arthritis. Arthritis Rheumatol. 2016;68(5):1060-71.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
3. Simponi™Aria® injection for intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc; 2019.
4. Singh JA, Saag KG, Bridges L Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care Res. 2016;68(1):1-26.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.