Golimumab (Simponi®, Simponi Aria®)	Place of Service Home Health Administration Infusion Center Administration Office Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] Self-Administration *(Simponi SC may be covered under the pharmacy benefit)* HCPCS Simponi Aria (IV): J1602 per 1 mg Simponi (SC): J3590

Conditions listed in policy (*see criteria for details*)

- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis
- Spondyloarthritis
- Ulcerative colitis

AHFS therapeutic class: disease-modifying antirheumatic agent (DMARD)

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

(1) Special Instructions and pertinent Information

Subcutaneous (SC) Simponi is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request for SC Simponi to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

Intravenous (IV) Simponi Aria is managed under the Medical Benefit, please submit clinical information for prior authorization review.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, Medi-Cal, and when applicable, ASO, Shared Advantage and HMO (non-direct contract)** 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.

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

1. Patient is receiving their first infusion or is being re-initiated 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 the medication based on documentation submitted.

3. Patient continues to experience moderate to severe adverse events on the medication 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.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Simponi®(golimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Polyarticular juvenile idiopathic arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response or intolerance to a disease modifying anti-rheumatic drugs or documented medical justification why methotrexate cannot be used, **AND**
3. Not used in combination with a targeted immunomodulator, **AND**
4. Inadequate response or intolerable side effect with at least two of the following: anti-TNFs, or JAK inhibitors

Covered Doses
Up to 80 mg/m^2 IV infusion at weeks 0 and 4, and every 8 weeks thereafter

Coverage Period
Cover yearly

ICD-10:
M08.00-M08.40

Psoriatic arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
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, **AND**
3. Not being used in combination with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors, Otezla), **AND**
4. One of the following:
    a. ***Effective through 3/4/2023***, either of the following:
        a. Inadequate response or intolerable side effect with at least two of the following drugs or drug classes: anti-TNFs, JAK inhibitors, IL-6 inhibitors, or Orencia (abatacept), OR
        b. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra and Renflexis), or contraindication to all infliximab products

    OR

    b. ***Effective 3/5/2023 and after***: Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis) or contraindication to all infliximab products

Covered Doses
SQ: Up to 50 mg SC injection once a month
IV: Up to 2 mg/kg IV infusion at weeks 0 and 4, then every 8 weeks

Coverage Period
Yearly based upon continued response to therapy

ICD-10:
L40.50-L40.59

Rheumatoid arthritis

1. Prescribed by or in consultation with a rheumatologist**, AND**
2. Inadequate response, intolerable side effect, or contraindication to methotrexate**, AND**
3. Not used in combination with another targeted immunomodulator (e.g., TNF inhibitors, IL-6 inhibitors, JAK inhibitors), **AND**
4. One of the following:
    c. ***Effective through 3/4/2023***, either of the following:
        c. Inadequate response or intolerable side effect with at least two of the following drugs or drug classes: anti-TNFs, JAK inhibitors, IL-6 inhibitors, or Orencia (abatacept), OR
        d. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra and Renflexis), or contraindication to all infliximab products

    OR

    d. ***Effective 3/5/2023 and after***: Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis) or contraindication to all infliximab products

Covered Doses
SQ: Up to 50 mg SC injection once a month
IV: Up to 2 mg/kg IV infusion at weeks 0 and 4, then every 8 weeks

Coverage Period
Yearly based upon continued response to therapy

ICD-10: (X=0-9)
M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

Spondyloarthritis

1. Prescribed by or in consultation with a rheumatologist**, AND**
2. ONE of the following:
    a. Inadequate response with a trial of any two-prescription strength NSAIDs, OR
    b. Intolerable GI adverse events after a trial of a prescription strength NSAID in combination with a PPI, OR
    c. Unable to take NSAIDs due to history of GI bleed

    AND
3. Not being used with other targeted immunomodulators (i.e., anti-TNFs, interleukin inhibitors), **AND**
4. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra, or Renflexis), or contraindication to all infliximab products

Covered Doses
SQ: Up to 50 mg SC injection once a month
IV: Up to 2 mg/kg IV infusion at weeks 0 and 4, then every 8 weeks

Coverage Period
Yearly based upon continued response to therapy

ICD-10: M45.0-M45.9

Ulcerative colitis

1. Not used with a targeted immunomodulator, **AND**
2. One of the following:
    a. ***Effective through 3/4/2023***, either of the following:
        i. Inadequate response or intolerable side effect with two targeted agents (i.e., Humira, Stelara, Xeljanz/Xeljanz XR), OR
        ii. Patient has had an inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra and Renflexis), or contraindication to all infliximab products

    OR

    b. ***Effective 3/5/2023 and after***: Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis) or contraindication to all infliximab products

Covered Doses
Up to 200 mg SC on week 0, 100 mg SC on week 2, followed by 100 mg SC thereafter every 4 weeks

Coverage Period
Initial authorization: 6 weeks
Reauthorization: Yearly based on continued response to therapy

ICD-10:
K51.00-K51.519, K51.8-K51.919

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Simponi® (golimumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use with other targeted immunomodulators

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
Simponi SC:

- 50 mg, 100 mg (prefilled syringe or single-dose prefilled SmartJect autoinjector)

Simponi Aria (IV):

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

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- 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.
- Gossec L, Smolen JS, Gaujoux-Viala C et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. Ann Rheum Dis 2012; 71:4-12.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384-413.
- Simponi® (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 9/2019.
- Simponi Aria® prescribing information. Janssen Biotech Inc. Horsham, PA. 2/2021.
- 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.
- Van Der Heijde D, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondylarthrosis. Ann Rheum Dis 2017;0:1-14."
- Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheum 2015;68:282-98.

(7) Policy Update

Date of last review: 4Q2022
Date of next review: 4Q2023
Changes from previous policy version:

- Section (2): Plaque psoriasis, Rheumatoid arthritis, and Ulcerative colitis –
  - Added qualifying step therapy with the use of preferred infliximab (Avsola, inflectra or Renflexis).
  - ***Effective 3/5/2023 and after***, will require step therapy with preferred infliximab (Avsola, Inflectra or Renflexis), and remove qualifying step therapy with 2 targeted agents

Rationale: Selection of preferred drugs is supported by similar safety and efficacy and are guideline supported agents.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee