ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Simponi® ARIA (golimumab) IV – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Simponi® ARIA (golimumab) IV

Diagnosis (documentation supportive of diagnosis is required)

IV Formulation ONLY:
☐ Active Rheumatoid Arthritis (Moderate to Severe)
☐ Other (please state): _____

Clinical Consideration

For Rheumatoid Arthritis, *monotherapy* is not indicated.

☐ Patient will receive concomitant therapy with methotrexate

Physician Specialty

☐ Rheumatology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

Prescriber or Authorized Signature: Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Simponi® ARIA (golimumab)

CLASSIFICATION

- Immune modulator, Tumor Necrosis Factor Inhibitor

DESCRIPTION

- Golimumab is a human monoclonal antibody that binds to both soluble and transmembrane bioactive forms of human TNFα. The interaction prevents TNFα from binding to its receptors, resulting in inhibition of the biological activity of TNFα. TNFα activity is associated with several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.
- Golimumab in combination with methotrexate is indicated for the subQ or IV treatment of moderately to severely active rheumatoid arthritis in adults. The safety and efficacy of switching between subQ and IV formulations and routes have not been established. Simponi ARIA is the IV formulation.
- Golimumab IV in combination with methotrexate was more effective in achieving a 20% improvement in the symptoms of RA compared with methotrexate alone (59% vs 25%) following 14 weeks of treatment in a multicenter, randomized, double-blind, controlled trial in 592 patients who were ≥ 18 years of age with moderately to severely active RA despite concurrent MTX therapy and had not previously been treated with a biologic TNF-blocker.
- Most common adverse reactions (incidence ≥3%) are upper respiratory tract infection, viral infection, bronchitis, hypertension, and rash.
- Care should be taken when switching from one biologic to another due to overlapping biological activity that may further increase the risk of infection.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 6
Commercial Formulary: Tier 6
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Simponi ARIA (golimumab) meets the definition of **medical necessity** for all FDA-approved indications not otherwise excluded from Part D including the following:

- Rheumatoid arthritis, moderately to severely active disease. Must be in combination with methotrexate.

***Documentation supportive of diagnosis and use in combination with methotrexate is required.*

Simponi ARIA (golimumab) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported.
- Simponi ARIA will not be approved for FDA approved indications for the subcutaneous formulation of Simponi. *Refer the Simponi Prior Authorization form for the following indications:*
    - Active Psoriatic Arthritis
    - Active Ankylosing Spondylitis

- Moderate to Severe Ulcerative Colitis

Required Provider Specialty:
- Approval is limited to Rheumatologist

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):
- Moderate to Severe Active Rheumatoid arthritis, in combination with methotrexate: 2 mg/kg IV infusion over 30 minutes at weeks 0 and 4, then every 8 weeks in combination with methotrexate

PRECAUTIONS

Black Box Warning:
Serious Infections: Patients treated with golimumab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue golimumab if a patient develops a serious infection. Reported infections with TNF blockers, of which golimumab is a member, include:
  - Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before golimumab use and during therapy. Initiate treatment for latent TB prior to golimumab use.
  - Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
  - Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.
- Consider the risks and benefits of treatment with golimumab prior to initiating therapy in patients with chronic or recurrent infection.
- Monitor patients closely for the development of signs and symptoms of infection during and after treatment with golimumab, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Malignancy: Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which golimumab is a member.

Precautions:
- Serious infections: Do not start Simponi ARIA during an active infection. If an infection develops, monitor carefully, and stop Simponi ARIA if infection becomes serious.
- Invasive Fungal infections: For patients who develop a systemic illness on Simponi ARIA, consider empiric antifungal therapy for those who reside in or travel to regions where mycoses are endemic.
- Hepatitis B reactivation: Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop Simponi ARIA and begin anti-viral therapy.
- Malignancies: More cases of lymphoma have been observed among patients receiving TNF-blockers compared with patients in the control groups. Cases of other malignancies have been observed among patients receiving TNF-blockers.
- Heart Failure: Worsening, or new onset, may occur. Stop Simponi ARIA if new or worsening symptoms occur. Demyelinating disease, exacerbation or new onset, may occur.

- Hypersensitivity reactions: Serious systemic hypersensitivity reactions including anaphylaxis may occur.

Billing/Coding information

CPT Coding:

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

HCPCS Coding:

J1602	Injection, golimumab, 1 mg, for intravenous use (For billing prior to 1/1/14 use C9399 or J3590)

COST

- AWP (March 2014): Simponi® ARIA™, 50mg/4 ml IV infusion (1 vial): $1,447.50

COMMITTEE APPROVAL

- February 2010 (Simponi®, subcutaneous injection)
- September 2013 (Simponi® ARIA™, line-extension)

GUIDELINE UPDATE INFORMATION

September 2013	Prior authorization and coverage policy created for Simponi ARIA
May 2014	Coverage policy updated

REFERENCES

- DRUGDEX®, accessed 09/13/2013, 5/12/2014
- Product Information: Simponi® ARIA™ (golimumab), Injection for intravenous use. Janssen Biotech, Inc., Horsham, PA, 2/2014.