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® (golimumab) – 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® (golimumab)

Diagnosis (documentation supportive of diagnosis is required)

☐ Active Rheumatoid Arthritis (Moderate to Severe)
☐ Active Psoriatic Arthritis (alone or in combination with methotrexate)
☐ Active Ankylosing Spondylitis
☐ Ulcerative Colitis (moderately to severely active)
☐ Other (please state): _____

Clinical Consideration (for approval, indicate and provide documentation of the following):

☐ **Diagnosis of Rheumatoid Arthritis ONLY: *Monotherapy* is not indicated for RA**

☐ Patient will receive concomitant therapy with methotrexate

☐ **Diagnosis of Ulcerative Colitis ONLY (for approval, provide documentation of the following):**

☐ Patient with corticosteroid dependence AND an inadequate response or intolerance to oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:

-inducing and maintaining clinical response
-improving endoscopic appearance of mucosa during induction
-inducing clinical remission
-achieving and sustaining clinical remission in induction responders

List therapies and provide supporting medical records: _____

Physician Specialty

☐ Rheumatology
☐ Dermatology
☐ Gastroenterology
☐ 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® (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.
- In the GO-RAISE trial (n=365), golimumab was superior to placebo in the number of adults achieving a 20% improvement in the Assessment in Ankylosing Spondylitis score (ASAS20) following 14 weeks of treatment. Adult patients were included if they had active AS disease for at least 3 months based on the modified New York criteria, with symptoms of active disease defined as a Bath AS Disease Activity Index score of 4 or greater, and with a visual analog scale for total back pain of 4 or greater (scale 0 to 10 centimeters), all despite current or previous treatment with NSAIDs or disease-modifying anti-rheumatic drugs (DMARDs). Concomitant use of stable doses of methotrexate, sulfasalazine, hydroxychloroquine, corticosteroids, and NSAIDs was allowed, however, prior use with other DMARDs, immunosuppressants, leflunomide, anti-tumor necrosis factor therapies were excluded. The results of the study may have been limited by differences between treatment groups in the disease duration at baseline and a history of extraaxial involvement.
- In the GO-REVEAL trial (n=405), golimumab was superior to placebo in the number of adults achieving a 20% improvement in the symptoms of psoriatic arthritis (PsA) following 14 weeks of treatment. This improvement in symptoms was seen regardless of methotrexate use. Adult patients were included if they had active PsA disease (3 swollen and 3 tender joints, negative rheumatoid factor, and a lesion at least 2 centimeters in diameter) despite treatment with NSAIDs or disease-modifying antirheumatic drugs. Concomitant use of stable doses of methotrexate, corticosteroids (not exceeding equivalent prednisone 10 milligrams (mg) once daily), and NSAIDs was allowed, however, patients with any previous use of anti-tissue necrosis factor agents were excluded.
- In the GO-FORWARD trial (n=444), golimumab in combination with methotrexate was superior to methotrexate alone in achieving a 20% improvement in the symptoms of active rheumatoid arthritis (RA) following 14 weeks of treatment and a significant improvement in the Health Assessment Questionnaire-disability index (HAQ-DI) score at week 24. Adult patients were included if they had active RA based on the American College of Rheumatology criteria (with at least 4 swollen and 4 tender joints) despite methotrexate 15 to 25 milligrams (mg) per week for at least 3 months. Concomitant use of oral corticosteroids (not exceeding equivalent prednisone 10 mg once daily) and NSAIDs was allowed but use of other disease modifying antirheumatic drugs or anti-tissue necrosis factor inhibitors were prohibited.
- Golimumab was effective for the treatment of active rheumatoid arthritis in biologic TNFα blocker *treatment-experienced* adults [previously treated with 1 or more doses of a TNFα blocker without treatment in at least the previous 8 (etanercept or adalimumab) to 12 weeks (infliximab)] compared with placebo according to a randomized, double-blind, controlled trial (n=461).
- Most common adverse reactions that occurred in >5% of Simponi-treated patients include upper respiratory tract infection and nasopharyngitis. The most serious adverse reactions were serious infections and malignancies.

- Golimumab is indicated in adults for the treatment of moderately to severely active ulcerative colitis in patients with corticosteroid dependence and an inadequate response or failure to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.
- Efficacy for golimumab for Ulcerative Colitis was demonstrated in a randomized, double-blind, controlled induction trial (UC-1; n=771) and maintenance trial (UC-2; n=463). Clinical response at 6 weeks was achieved by statistically significantly more patients with golimumab compared with placebo (52% vs. 30%). Among patients who achieved a clinical response, the response was maintained to week 54 in significantly more patients who continued to receive golimumab compared with placebo (51% vs. 31%) in the maintenance trial of patients with moderately to severely active ulcerative colitis, corticosteroid dependence, and an inadequate response or failure to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.
- 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 5
Commercial Formulary: Tier 6
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Simponi (golimumab) meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including the following:

- Active Ankylosing spondylitis
- Active Psoriatic arthritis (alone or in combination with methotrexate)
- Rheumatoid arthritis, moderately to severely active disease. Must be in combination with methotrexate.
- Ulcerative Colitis that is moderately to severely active in patients with corticosteroid dependence AND an inadequate response or intolerance to oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:
  -inducing and maintaining clinical response
  -improving endoscopic appearance of mucosa during induction
  -inducing clinical remission
  -achieving and sustaining clinical remission in induction responders

***Documentation of diagnosis and supporting information for the patient's medical record is required for all indications.*

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

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Rheumatologist, Dermatologist or Gastroenterologist

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- **Active Ankylosing spondylitis:** 50 mg subQ once monthly with or without methotrexate or other nonbiologic disease modifying antirheumatic drugs (DMARDs). Patients may continue concomitant treatment with corticosteroids, nonbiologic DMARDs and/or NSAIDs while receiving golimumab.
- **Active Psoriatic arthritis, alone or in combination with methotrexate:** 50 mg subQ once monthly with or without methotrexate or other nonbiologic DMARDs. Patients may continue concomitant treatment with corticosteroids, nonbiologic DMARDs and/or NSAIDs while receiving golimumab.
- **Moderate to Severe Active Rheumatoid arthritis, in combination with methotrexate:** 50 mg subQ once a month in combination with methotrexate. Patients may continue concomitant treatment with corticosteroids, nonbiologic DMARDs and/or NSAIDs while receiving golimumab.
- **Moderate to Severe Active Ulcerative colitis:** recommended adult induction dose is 200 mg subQ at week 0, followed by 100 mg subQ at week 2, then maintenance therapy with 100 mg subQ every 4 weeks.

PRECAUTIONS

- **Black Box Warning:**
  - Tuberculosis (TB), invasive fungal infections, bacterial, viral, and other opportunistic infections, some fatal, have been observed in patients receiving golimumab. Patients should be evaluated for TB risk factors and be tested for latent TB infection prior to and during golimumab therapy. Treatment of latent TB infection should be initiated prior to therapy with golimumab. Monitor patients for signs and symptoms of infection including TB in patients who tested negative for latent TB infection. Lymphoma and other malignancies, some fatal, have been reported in pediatric patients 18 years of age or less (not indicated in this population) treated with tissue necrosis factor blockers.
- Hepatosplenic T-cell lymphoma has been reported primarily in adolescents and young adults receiving TNF blockers for Crohn's disease or ulcerative colitis; most cases were fatal and occurred with concomitant use of azathioprine or mercaptopurine
- Serious infections (e.g. bacterial (Legionella and Listeria), tuberculosis, invasive fungal infections, viral, parasitic, and other opportunistic infections), including fatalities, have been reported; do not initiate therapy in patients with active infections (including chronic or localized infections); monitoring recommended in all patients; stop golimumab if infection becomes serious.
- Evaluate risk/benefit prior to initiation of golimumab due to increased risk of infection in patients with chronic or recurring infections, a history of opportunistic infection, comorbid conditions, receiving concomitant immunosuppressants or switching from another biological disease modifying antirheumatic drug, or who have traveled or lived in areas of endemic TB or mycoses.
- Reactivation or new onset of tuberculosis may occur; increased risk in patients with potential exposure due to travel or residence in endemic areas, close personal contact with active TB, or with history of latent or active disease, regardless of previous Bacille Calmette-Guerin vaccination.
- Auto-antibody formation has occurred, including development of a lupus-like syndrome
- Concomitant use of abatacept or anakinra is not recommended.
- Concomitant use of live vaccines is not recommended.
- Congestive heart failure, new onset or worsening of preexisting disease, has been reported; monitoring is recommended.
- Demyelinating disorders, CNS and peripheral (e.g. multiple sclerosis, Guillain-Barré syndrome); new onset or worsening of preexisting condition have been reported; stop golimumab if disorders develop.

- Elderly patients > 65 years of age are at increased risk of infection.
- Hematologic cytopenias (leukopenia, neutropenia, thrombocytopenia, and pancytopenia) have been reported.
- Hepatitis B virus, chronic carriers; reactivation has occurred, including fatalities; monitoring is recommended; discontinuation and supportive treatment may be necessary.
- Hypersensitivity reactions, including anaphylaxis, have been reported.
- Latex-sensitivity: allergic reactions may occur in latex-sensitive patients; the needle cover of prefilled syringe and autoinjector prefilled syringe contain dry natural rubber, a latex derivative.
- Leukemia, acute or chronic, has been reported in patients being treated for arthritis and other indications with tumor necrosis factor blockers.
- Malignancies, history or new-onset, or conditions with malignancy risk have greater risk of developing other malignancies.

Billing/Coding information

CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS Coding:

C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics

COST

- AWP (November 2011): Simponi® 50mg/0.5ml subQ injection (1): $2,329.98
- AWP (May 2013): Simponi® 50mg/0.5ml subQ injection (1): $2,846.33
- AWP (May 2013): Simponi® 100mg/1ml subQ injection (1): $3,273.28

COMMITTEE APPROVAL

- February 2010

GUIDELINE UPDATE INFORMATION

February 2010	Medical Policy created
November 2011	Coverage Policy created
May 2013	Coverage Policy updated to include Ulcerative Colitis indication for Part D 2014

REFERENCES

- DRUGDEX®, accessed 11/30/2011, 05/21/13
- Product Information: Simponi® (golimumab), solution for subcutaneous injection. Janssen Biotech, Inc, Horsham, PA, 2011.