



Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Active Rheumatoid Arthritis (Moderate to Severe) <input type="checkbox"/> Active Psoriatic Arthritis <i>Note: Alone or in combination with methotrexate</i> <input type="checkbox"/> Active Ankylosing Spondylitis	<input type="checkbox"/> Other (please state): _____ _____ _____ _____
Clinical Consideration for Rheumatoid Arthritis	For Rheumatoid Arthritis, <i>monotherapy</i> is not indicated. <input type="checkbox"/> Patient will receive concomitant therapy with methotrexate.	
Physician Specialty	<input type="checkbox"/> Rheumatology <input type="checkbox"/> Dermatology	<input type="checkbox"/> Other (please state): _____
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required): _____ Please attach a copy of the prescription or provide ALL of the information below: Simponi [®] (golimumab) Strength _____ Sig _____ Qty _____ Refills _____ *Please attach all relevant medical records and test results* We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

Prescriber Signature

Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

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 TNF α . The interaction prevents TNF α from binding to its receptors, resulting in inhibition of the biological activity of TNF α . TNF α 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 TNF α blocker *treatment-experienced* adults [previously treated with 1 or more doses of a TNF α 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.
- 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 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.

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 Rheumatology or Gastroenterology

DOSAGE/ADMINISTRATION

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

- Ankylosing spondylitis: 50mg subQ once a month
- Psoriatic arthritis: 50mg subQ once a month (monotherapy or in combination with methotrexate)
- Rheumatoid arthritis: 50mg subQ once a month in combination with methotrexate.

PRECAUTIONS

- **Black Box Warning:**
 - Tuberculosis, invasive fungal infections, bacterial, viral, and other opportunistic infections, some fatal, have been observed in patients receiving golimumab. Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to and during golimumab therapy. Treatment of latent tuberculosis infection should be initiated prior to therapy with golimumab. Monitor patients for signs and symptoms of infection including tuberculosis in patients who tested negative for latent tuberculosis 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
-------	------------------------

ICD-9 Diagnoses Codes That Support Medical Necessity:

696	Psoriasis and similar disorders
-----	---------------------------------

696.0	Psoriatic arthropathy
-------	-----------------------

714	Rheumatoid arthritis and other inflammatory polyarthropathies
-----	---

714.0	Rheumatoid arthritis
-------	----------------------

720	Ankylosing spondylitis and other inflammatory spondylopathies
-----	---

720.0	Ankylosing spondylitis
-------	------------------------

COST

- AWP (November 2011): Simponi® 50mg/0.5ml subQ injection (1): \$2,329.98

COMMITTEE APPROVAL

- February 2010

GUIDELINE UPDATE INFORMATION

February 2010	Medical Policy created
---------------	------------------------

November 2011	Coverage Policy created
---------------	-------------------------

REFERENCES

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