


MEDICAL POLICY STATEMENT		
Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	06/15/2012	06/15/2011
Author		
Shelley Jones RN, CCM, Wendy Null RPh		



CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

## A. SUBJECT

### Golimumab (Simponi) Injection

## B. BACKGROUND

Golimumab (Simponi) is a human monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNF. This interaction prevents the binding of TNF to its receptors, thereby inhibiting the biological activity of TNF (a cytokine protein). There was no evidence of the golimumab antibody binding to other TNF superfamily ligands; in particular, the golimumab antibody did not bind or neutralize human lymphotoxin. Golimumab (Simponi) did not lyse human monocytes expressing transmembrane TNF in the presence of complement or effector cells.

Elevated TNF levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases, such as rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. TNF is an important mediator of the articular inflammation that is characteristic of these diseases. Golimumab (Simponi) modulated the *in vitro* biological effects mediated by TNF in several bioassays, including the expression of adhesion proteins responsible for leukocyte infiltration (E-selectin, ICAM-1 and VCAM-1) and the secretion of proinflammatory cytokines (IL-6, IL-8, G-CSF and GM-CSF).

The patient selection criteria outlined was derived from the FDA-approved prescribing information for golimumab (Simponi), the studies that were presented to the FDA in support of the pre-market approval application, and studies in the peer-reviewed published medical literature. The FDA label indication that is found in the manufacturer prescribing information and is described below are rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Coverage decisions for conditions other than the above FDA-approved indication will be reviewed on a case-by-case basis if proven effective through research documentation. The requesting provider will need to support his exception request with the appropriate literature.

## C. POLICY

---

CareSource will approve the use of golimumab (Simponi) and consider its use as medically necessary when the following criteria have been met for:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis

**All other uses of golimumab (Simponi) are considered experimental/investigational, and therefore, not covered.**

### **Rheumatoid Arthritis**

Golimumab (Simponi) is indicated alone or in combination with methotrexate for the treatment of adult patients (18 years and older) with moderately to severely active rheumatoid arthritis.

Prior Authorization Criteria:

- Documented diagnosis of moderate to severe active rheumatoid arthritis
  - Prescribed by a rheumatologist or under recommendation of rheumatologist
  - Failure of one non-biological DMARD or biologic DMARD
- OR**
- Unable to tolerate or has a medical contraindication of conventional therapies

### **Ankylosing Spondylitis**

Golimumab (Simponi) is indicated for the treatment of adult patients (18 years and older) alone or in combination with methotrexate with active ankylosing spondylitis.

Prior Authorization Criteria:

- Documented diagnosis of active ankylosing spondylitis
  - Prescribed by a rheumatologist or under recommendation of rheumatologist
  - BASDI (Bath ankylosing spondylitis disease activity index) score of greater than or equal to 4. ([www.Spondylitis.org](http://www.Spondylitis.org) and [www.asas-group.org](http://www.asas-group.org))
  - Failure of at least one non-biological DMARD in patients without pure axial disease. If pure axial disease, no requirement for DMARD failure
- OR**
- Unable to tolerate or has a medical contraindication of conventional therapies

### **Psoriatic Arthritis**

Golimumab (Simponi), alone or in combination with methotrexate, is indicated for the treatment of adult patients (18 years and older) with active psoriatic arthritis.

Prior Authorization Criteria:

- Documented diagnosis of active psoriatic arthritis
  - Failure of a trial of at least one non-biological DMARD
- OR**
- Unable to tolerate or has a medical contraindication of conventional therapies

**Note: Documented diagnosis must be confirmed by portions of the individual's medical record, which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to, test reports, chart notes from provider's office or hospital admission notes.**

**For Special Needs Plan members reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):**

## **For Medicare**

### **NCD for golimumab (Simponi)**

Medicare does not have a National Coverage Determination (NCD) for golimumab (Simponi). In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at:

<http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>.

Local Coverage Determinations (LCDs) for golimumab (Simponi) do not exist at this time. (Accessed February 18, 2011)

### **Safety**

CareSource will only review requests for **golimumab (Simponi)** if the patient has **none** of the following contraindications:

- Hypersensitivity to golimumab
- Active serious infections, or a history of recurrent infections including invasive fungal infections, bacterial, viral and other infections caused by opportunistic pathogens
- Patient has Tuberculosis (active, untreated or reactivation of latent TB), or contact with person with active TB or traveled to countries with high incidence of TB, or other active serious infections, or a history of recurrent infections including invasive fungal infections, bacterial, viral and other infections caused by opportunistic pathogens
- Patient has not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis
- Patient is positive for hepatitis B during therapy or there is evidence of no recovery from prior hepatitis B infection
- Patient is going to have concurrent use with tumor necrosis factor antagonists
- Patient has a diagnosis of Lymphoma and other malignancies
- Patient currently receiving antineoplastic, immunosuppressant or immunomodulating agents
- Patient with congestive heart failure
- Patient with active hepatic disease or hepatic impairment
- Patient with preexisting or recent-onset demyelinating disorders
- Patient is not up to date with all immunizations in agreement with current immunization guidelines prior to initiating the therapy (patient may not be given live vaccines concurrently with golimumab (Simponi), and the interval between vaccination and initiation of golimumab (Simponi) therapy must in accordance with current vaccination guidelines)

**Pregnancy Risk Factor = B**

There are no adequate and well-controlled studies of golimumab (Simponi) in pregnant women. Because animal reproduction and developmental studies are not always predictive of human response, it is not known whether golimumab (Simponi) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Only use golimumab (Simponi) during pregnancy if clearly needed.

It is not known whether golimumab (Simponi) is excreted in human milk or absorbed systemically after ingestion. Because many drugs and immunoglobulins are excreted in human milk, and because of the potential for adverse reactions in breastfeeding infants from golimumab (Simponi), decide whether to discontinue breastfeeding or the drug, taking into account the importance of the drug to the mother.

**Conditions of Coverage**

<b>Quantity Limitations</b>	50mg injection per month	
<b>J-Code</b>	J3590	
<b>NDC</b>	57894007001 57894007002	
<b>Applicable ICD-9 Codes</b>	714.0-714.2	Rheumatoid Arthritis [moderately to severely active in adults]
	720.0	Ankylosing spondylitis
	696.0	Psoriatic arthritis
<b>Place Of Service</b>	Office, Outpatient, Home <b>**Preferred place of service is in the home.</b> <b>Note:</b> CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost-effective setting that are supportive of the patient's medical condition and unique needs and condition.  The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.	
<b>Authorization Period</b>	Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. All authorizations are subject to continued eligibility.	

## D. REVIEW / REVISION HISTORY

---

6/15/2011

## E. REFERENCES

---

Simponi [package insert]. Horsham, PA: Centocor Ortho Biotech Inc.; December 2010.

Winifred S. Hayes, Inc. *Infliximab for Rheumatoid Arthritis*. [www.hayesinc.com](http://www.hayesinc.com) Published: April 29, 2004 (February 8, 2011)

FDA Approves New Drug for Rheumatoid Arthritis; Pharmacist's Letter; March 2010; Vol: 26

Rheumatoid arthritis: the role of DMARDs. Pharmacist's Letter/Prescriber's Letter 2009;25(2):250210.

Saag, KG., et al. American College of Rheumatology 2008 *recommendations for the use of nonbiological and biological disease-modifying antirheumatic drugs in rheumatoid arthritis*. *Arthritis & Rheumatology (Arthritis Care & Research)*, 59:6, 2008, June 15.

American College of Rheumatology 2008 *Recommendations for the use of non biologic and biologic disease modifying antirheumatic drugs in rheumatoid arthritis*. *Arthritis & Rheumatism (Arthritis Care & Research)* Vol. 59. No. 6. June 15. 2008: 762-784, DOI 10. 1002/art.23721

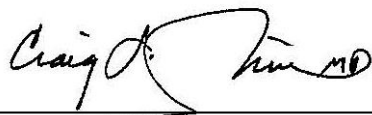
Wolters Kluwer. Facts & Comparisons. [www.factsandcomparisons.com](http://www.factsandcomparisons.com), 2011. (February 15, 2011)

Kavanaugh A, McInnes I, Mease P, et al, "Golimumab, a New Human Tumor Necrosis Factor  $\alpha$  Antibody, Administered Every Four Weeks as a Subcutaneous Injection in Psoriatic Arthritis, Twenty-Four-Week Efficacy and Safety Results of a Randomized, Placebo-Controlled Study," *Arthritis Rheum*, 2009, 60(4):976-86.[PubMed 19333944]. (February 17, 2011).

Inman RD, Davis JC Jr, van der Heijde D, et al, "Efficacy and Safety of Golimumab in Patients With Ankylosing Spondylitis, Results of a Randomized, Double-Blind, Placebo-Controlled, Phase III Trial," *Arthritis Rheum*, 2008, 58(11):3402-12.[PubMed 18975305]. (February 17, 2011).

U.S. Food and Drug Administration Information for Healthcare Professionals: Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Enbrel, Humira, Cimzia, and Simponi). <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124185.htm>. Accessed February 25, 2011.

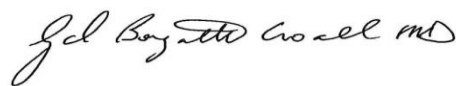
**The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**



Chief Medical Officer

June 2, 2011

Date



Senior Medical Director

June 2, 2011

Date