

## Pharmacy Policy Bulletin

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**Title:** Golimumab (Simponi™)

**Policy #:** FS.CLIN.21

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### Intent

**Golimumab (Simponi™)** is a tumor necrosis factor (TNF) blocker indicated for the treatment of moderately to severely active Rheumatoid Arthritis (RA) in adults in combination with methotrexate, Active Psoriatic Arthritis (PsA) in adults alone or in combination with methotrexate, and Active Ankylosing Spondylitis in adults (AS).

The use of golimumab (Simponi™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

### Description:

**Golimumab (Simponi™)** is a humanized monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNF $\alpha$  (tumor necrosis factor alpha). This interaction prevents the binding of TNF $\alpha$  to its receptors, thereby inhibiting the biological activity of TNF $\alpha$ . Elevated TNF $\alpha$  levels in the blood, synovium, and joints have been implicated in the pathophysiology of several chronic inflammatory diseases such as rheumatoid arthritis (RA), psoriatic arthritis (PA), and ankylosing spondylitis. TNF $\alpha$  is an important mediator of the articular inflammation that is characteristic of these diseases. It is believed that the inhibition of TNF $\alpha$  can lead to a reduction in the signs and symptoms of the aforementioned diseases. Currently there are over 5 agents that treat RA, Psoriatic Arthritis, and Ankylosing Spondylitis. Of those agents, 4 of them work by inhibiting the binding of TNF $\alpha$  to its receptors.

### Policy

**Golimumab (Simponi™)** is approved when the following inclusion criterion is found:

- Documentation of diagnosis of moderately to severely active Rheumatoid Arthritis (RA), Ankylosing Spondylitis, or Psoriatic Arthritis (PA) and **all** of the following:
  - Patient is an adult ( $\geq$  18 years)
  - Concurrent use with methotrexate (RA only)
  - Trial, failure or contraindication to adalimumab (Humira)
  - Trial, failure or contraindication to etanercept (Enbrel)
  - Patient does not have concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
  - Patient does not have active infections or sepsis
  - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
  - Patient does not have active malignancy

## Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

## References

Simponi® (golimumab). In: Facts and Comparisons [www.factsandcomparisons.com](http://www.factsandcomparisons.com) Indy, IN: Walter Kluwer Health Inc. Accessed October 27, 2011.

Simponi® (golimumab). In: Drugdex [www.micromedex.com](http://www.micromedex.com). Greenwood Village, CO: Thomson Micromedex. Accessed October 27, 2011.

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

## Applicable Drugs

**i** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Golimumab (Simponi)	All

## Cross References

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**Policy version number:** 3.00  
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**Policy effective date:** 12/1/2011  
**Next required review date:** 9/8/2012

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