Policies Repository

Independence Blue Cross

Policy Title	Golimumab (Simponi™)
Policy Number	FS.CLIN.21

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy

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 (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Golimumab (Simponi™) is a humanized monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNFα (tumor necrosis factor alpha). This interaction prevents the

binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα. Elevated TNFα 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. TNFα is an important mediator of the articular inflammation that is characteristic of these diseases. It is believed that the inhibition of TNFα can lead to a reduction in the signs and symptoms of the aforementioned diseases. Currently there are over 5 agents that treat RA, Psoritatic Arthritis, and Ankylosing Spondilitis. Of those agents, 4 of them work by inhibiting the binding of TNFα to its receptors.

Policy Guideline Inclusion

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 and PA only)
  - Trial, failure or contraindication to adalibumab (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

Policy Guideline Exclusion

Golimumab (Simponi™) is denied when the following exclusion criterion is present:

- No 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 (≥ 18 years)
- Concurrent use with methotrexate (RA and PA only)
- Trial, failure or contraindication to adalibumab (Humira)
- Trial, failure or contraindication to etanercept (Enbrel)
- Patient does not have concurrent therapy with Anakinra (Kineret®) or othertumor 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

Policy List of Applicable Drugs

Brand Name	Generic Name
Simponi	golimumab

Dosing and Administration

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

Policy References

Simponi ® (golimumab). In: Facts and Comparisons www.factsandcomparisons.com Indy, IN: Walter Kluwer Health Inc. Accessed December 30, 2010.

Simponi ® (golimumab). In: Drugdex www.micromedex.com. Greenwood Village, CO: Thomson Micromedex. Accessed December 30, 2010.

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

Policy Link to Related Policies

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respective benefit programs, and do not constitute a contract. If you are an IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins.