



## Prior Authorization Approval Criteria

### *Simponi (golimumab)*

<b>Generic name:</b>	golimumab
<b>Brand name:</b>	Simponi
<b>Medication class:</b>	tumor necrosis factor (TNF) blocker
<b>FDA-approved uses:</b>	Moderate to severe rheumatoid arthritis Active psoriatic arthritis Active ankylosing spondylitis
<b>Available dosage forms:</b>	50 mg/0.5ml single-dose prefilled SmartJect autoinjector and as a 50 mg/0.5ml single dose prefilled syringe.
<b>Usual dose:</b>	50mg administered by subcutaneous injection once a month. Patients may self inject with proper training
<b>Approximate monthly cost:</b> (based on AWP 2009)	\$3957.50/month
<b>Duration of therapy:</b>	Indefinite

#### **Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- **Rheumatoid Arthritis:**
  - Clinically diagnosed rheumatoid arthritis.
  - Must be used in combination with methotrexate.
  - Failed/intolerant to at least one DMARD.
  - Failed/intolerant to Enbrel and Humira.
- **Psoriatic Arthritis:**
  - Clinically diagnosed psoriatic arthritis.
  - Failed/intolerant to corticosteroids.
  - Failed/intolerant to methotrexate.
  - Failed/intolerant to Enbrel and Humira.
- **Ankylosing Spondylitis**
  - Clinically diagnosed ankylosing spondylitis.
  - Failed/intolerant to at least one DMARD.
  - Failed/intolerant to methotrexate.
  - Failed/intolerant to Enbrel and Humira.

#### **Caution:**

- Risk of serious infection.
- Hepatitis B reactivation
- Malignancies
- Heart failure
- Demyelinating disease

#### **Contraindication:**

- No contraindications listed at this time.

**Not approved if:**

- Patient does not meet the above stated criteria.

**Special considerations:**

**TNF Inhibitors**

<b>Drug</b>	<b>Formulation</b>	<b>Usual dose for rheumatoid arthritis</b>	<b>Cost</b>
Humira (adalimumab)	40 mg/0.8ml syringe	40 mg sc q2wks	\$1904.00/month
Cimzia (certolizumab)	200mg/ml	400 mg sc at 0,2 and 4 wks, then 200mg q 2wks or 400mg q 4wks	\$1720.00/dose
Enbrel (etanercept)	25 mg, 50mg/ml syringe	25 mg sc 2x/wk or 50 mg once/wk	\$1980.00/month
Simponi (golimumab)	50 mg/0.5ml syringe	50 mg sc once/mo	\$3957.50/month
Remicade (infliximab)	100 mg vial	5 mg/kg at 0, 2 and 6 wks, then every 8 wks	\$3132.00/dose (based on a 75kg patient)

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 09/09/09

Revised: 03/14/12