



SIMPONI™ UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Disease Modifying Anti-Rheumatic Drug (DMARD)
BRAND NAME:	Simponi™
GENERIC NAME:	Golimumab
Simponi is supplied as 50 mg/0.5 mL in a single dose prefilled SmartJect autoinjector, OR 50 mg/0.5 mL in a single dose prefilled syringe.	

FDA INDICATIONS:

Golimumab 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
- Active Ankylosing Spondylitis (AS) in adults.

COVERAGE AUTHORIZATION CRITERIA:

Coverage is provided if one of the following bullets applies:

- **Rheumatoid or Psoriatic Arthritis** when a patient has experienced a therapeutic failure/inadequate response with methotrexate
OR
Is unable to receive methotrexate (e.g. use of methotrexate is contraindicated in the patient)
OR
Rheumatoid or Psoriatic Arthritis is rapidly progressive and advancing.
- Diagnosis of **Ankylosing Spondylitis**

*Coverage of Simponi is not provided for use in combination with Kineret, Orencia, Remicade, Enbrel, Cimzia, or Humira.

*For all covered indications, the provider must have considered and screened for the presence of latent tuberculosis (TB) infection.

RISK OF SERIOUS INFECTIONS

- Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal, and other opportunistic infections have occurred in patients receiving golimumab.
- Golimumab should be discontinued if a patient develops a serious infection or sepsis.

- Perform test for latent TB; if positive, start treatment for TB prior to starting golimumab.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative

RATIONALE:

For RA and Psoriatic Arthritis, a treatment program that includes methotrexate as initial therapy may be considered for most patients unless a patient has a contraindication to or is unable to receive methotrexate (e.g., such as in the presence of liver or lung disease).

DOSAGE AND ADMINISTRATION:**Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis:**

- 50 mg administered by subcutaneous injection once a month
- To ensure proper use, allow the prefilled syringe or autoinjector to sit at room temperature outside the carton for 30 minutes prior to injection.

RISK FACTORS / CONTRAINDICATIONS:

- Serious Infections – Do not start golimumab during an active infection. If an infection develops, monitor carefully, and stop golimumab if infection becomes serious.
- Invasive fungal infections – For patients who develop a systemic illness on golimumab, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic.
- Hepatitis B reactivation – Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop golimumab and begin anti-viral therapy.
- Malignancies – The incidence of lymphoma was seen more often than in the general U.S. population. Cases of other malignancies have been observed among patients receiving TNF-blockers.
- Heart failure – Worsening, or new onset, may occur. Stop golimumab if new or worsening symptoms occur.
- Demyelinating disease, exacerbation or new onset, may occur.

DRUG INTERACTIONS:

- An increased risk of serious infections has been seen in clinical RA studies of other TNF-blockers used in combination with anakinra or abatacept, with no added benefit. The concomitant use of golimumab with other biologic agents such as Kineret, Orencia, Remicade, Enbrel, Cimzia, or Humira is not recommended.
- No data are available on the response to live vaccination or the risk of infection, or transmission of infection after the administration of live vaccines to patients receiving golimumab. Live vaccines should not be given concurrently with golimumab.

REFERENCES:

1. Simponi (golimumab). Product Information. Centocor Ortho Biotech, Inc. 2009.
2. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis & Rheumatism (Arthritis Care & Research)*. 2008; 59(6):762-784.
3. Barclay L. Guidelines Issued for Management of Psoriatic Arthritis. (From guidelines in the October 24, 2008 Online First issue of the *Annals of the Rheumatic Disease*.) <http://cme.medscape.com/viewarticle/582664>; accessed May 1, 2009.