

**Table 7.**

## Simponi (golimumab) [4, 24]

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### Initial Visit:

#### History and Physical

- History of CHF?**
- History of malignancy or serious infections (hepatitis, TB, HIV, other)?**
- History or family history of multiple sclerosis?**
  - History of other neurological disease including seizure disorders?
- Total body skin exam for skin cancer**
- Check for HSM, cervical/axillary/inguinal lymphadenopathy**
- For Remicade - History of COPD and smoking?
- History of diabetes?
- Have you lived in Southwest (risk of coccidiomycosis) or Southeast – Ohio and Mississippi River Valleys (risk of histoplasmosis or blastomycosis)?
- Travel to area endemic for TB?
- Live vaccine within past month – you or household member?
- Medications: Anakinra; cyclosporine; abatacept; natalizumab; other anti-TNF agents; rituximab; methotrexate; corticosteroids; cyclophosphamide (increased risk of solid malignancies in Wegener’s granulomatosis); warfarin (levels can be decreased by anti-TNF agents)
- Major surgery in next month?
- Active infection? Hold dose for infection or sepsis
- Latex allergy?
- History Wegener’s granulomatosis AND cyclophosphamide? (risk of malignancy)
- For Enbrel - History of alcoholism? (increased mortality in alcoholic hepatitis)

#### Labs

- CBC, CMP**
- TB test (for PPD, consider >5mm as positive)**
- Hepatitis B screen: Hepatitis B sAg, Hepatitis B sAb, Hepatitis B cAb**
- Influenza vaccine (if flu season)**
- Baseline ANA (optional)
- HIV (optional) – especially with erythrodermic psoriasis
- Cardiovascular risk panel: CRP, homocysteine, HbA1C, lipid profile (if screening for psoriasis) (optional)
- Pneumovax (optional)

#### Counseling/Other

- First injection under supervision of health care professional and instruction of proper disposal of needles**
- Can worsen existing malignancies**
- Malignancy: more frequently observed malignancies were lymphoma, non-melanoma skin cancer, and acute and chronic leukemia;** lymphoma and other malignancies in children and adolescents including Hodgkin's and non-Hodgkin's lymphoma;
  - for Humira, malignancies seen more than in controls; lymphoma more than in general population
  - for Remicade and Cimzia, non-melanoma skin cancer with prior phototherapy
  - for Remicade, breast and colorectal cancers were observed in trials
  - for Remicade, if h/o COPD and smoking, risk of lung or head and neck malignancy
  - for Remicade, hepatosplenic T-cell lymphoma - all in Crohn's or ulcerative colitis, mostly adolescent or young adult males AND azathioprine or 6-mercaptopurine at or prior to diagnosis (although rheumatologists frequently use this combination)
- Risk of reactivation of latent TB –**
  - risk is less with Enbrel than with TNF-blocking monoclonal antibodies
- Serious, sometimes fatal, infection** (especially with methotrexate or corticosteroids): bacterial (including sepsis), mycobacterial, invasive fungal, viral, and opportunistic infections, such as tuberculosis (including reactivation), histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, pneumocystosis, listeriosis
- Exacerbation or new onset of demyelinating disease, e.g., multiple sclerosis,** seizure disorder
  - Rare cases of optic neuritis, seizure, CNS manifestations of systemic vasculitis, peripheral demyelinating disorders such as Guillain-Barre syndrome; Caution with pre-existing demyelinating or seizure disorders
- Can worsen moderate to severe heart failure or cause new-onset heart failure**
- May lower incidence of coronary artery disease (a benefit)**
- Injection site reaction
- Anaphylaxis from injection (e.g., angioedema; bronchospasm; hypotension)
- Lupus-like syndrome
- Reactivation of hepatitis B
- Hepatotoxicity - acute liver failure, jaundice, hepatitis, cholestasis, autoimmune hepatitis; increased mortality with alcoholic hepatitis at six months
- Incidence of elevated liver enzymes and liver complications is somewhat higher with Remicade than with other TNF-alpha inhibitors<sup>4</sup>.
- Cytopenias: pancytopenia, aplastic anemia, leucopenia, thrombocytopenia
- Avoid live vaccines – self and household members
- Pediatric Patients: Up to date on vaccines before starting?
- Needle cap of the prefilled syringe and the autoinjector contain a latex derivative

- Formation of anti-Simponi antibodies, less with methotrexate, that can cause decreased efficacy over time
- For Enbrel - If you have diabetes, there is a risk for hypoglycemia and a higher chance for infection when serum glucose is poorly controlled
- For Simponi and Remicade - New-onset or worsening psoriasis
- For Cimzia - Erroneously elevated aPPT tests
- For Cimzia - Intestinal obstruction (with Crohn's patients)

**Follow-up Visit:**

History and Physical

- Every six months: Total body skin exam for skin cancer**
- Every six months: Check for HSM, cervical/axillary/inguinal lymphadenopathy**
- Any new infection – hold dose for active infection or sepsis
- Any signs of heart failure
- Major surgery in next month?
- Is there sustained clinical efficacy in the treatment interval? Skin? Joints?
- Any live vaccines in past month?
- Any household members getting live vaccine?
- Other interval history

Labs

- Every three months for first two follow-up visits, then every six months: CBC, CMP**
- Every year: TB test (consider induration of >5mm as positive)**
- Influenza vaccine annually (in flu season)**
- In HBV carriers, check liver panel for laboratory signs of hepatitis B reactivation
- ANA and anti-ds-DNA (if lupus-like symptoms)