Table 7.

Simponi (golimumab) [4, 24]

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?
  - o 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

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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;
  o for Humira, malignancies seen more than in controls; lymphoma more than in general population
  o for Remicade and Cimzia, non-melanoma skin cancer with prior phototherapy
  o for Remicade, breast and colorectal cancers were observed in trials
  o for Remicade, if h/o COPD and smoking, risk of lung or head and neck malignancy
  o 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 –
  o 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
  o 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
Cytopenias: pancytopenia, aplastic anemia, leukopenia, 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)