UNC INFLAMMATORY BOWEL DISEASE DRUG PROTOCOL

GOLIMUMAB (SIMPONI)

TREATMENT PROTOCOL:

Golimumab is a human monoclonal antibody that specifically binds to human tumor necrosis factor alpha (TNFα) and neutralizes its activity. It has a bioavailability of 53% and a half-life of ~ 2 weeks

Current IBD indications for golimumab at UNC

- **Ulcerative Colitis:**
  1. Induction and maintenance therapy for patients with moderate to severe disease who have had an inadequate response to conventional therapy*

Dosage and Route of Administration

- **Route of administration:** Subcutaneous Injection
- **Dosage forms and strength:** comes as 100 mg/1 ml in a single-dose **prefilled SmartJect (autoinjector)** or as 100 mg/1 ml in a single-dose **prefilled syringe**
- **Dose and intervals:**
  - Induction: 200 mg at week 0, followed by 100 mg at week 2
  - Maintenance: 100 mg (one injection) every 4 weeks

Higher dose or shorter intervals can be used based on the clinical situation

* FDA-approved indications

Time for Response

- Patients may feel better by the time of the second injection. It may take up to 6 weeks for a definitive clinical response.

Contraindications

- **Absolute:**
    1. Moderate or severe HF (New York Heart Association [NYHA] class III/IV)
    2. Active solid or hematological malignancies
    3. Active systemic infection
    4. Untreated latent TB

- **Relative/may use with caution:**
    1. Mild heart failure (NYHA functional class I or II)†
    2. History of demyelinating disease (MS, optic neuritis)‡
    3. Family history of demyelinating disease (MS, optic neuritis)
    4. History of solid or hematological malignancy within the past 5 years
    5. History of malignant melanoma
    6. Patients with multiple comorbid conditions that may increase risk of infections (tobacco use, DM, COPD)

Administration and Safety Monitoring

Before initiation of therapy:

- Careful medical history to assess for any absolute and relative contraindications

- Evaluate immunization status and provide any indicated vaccines (influenza, pneumonia, hepatitis B, HPV)

- Prior authorization: Email IBD nurse the patient's information
    - Anthea Darling, RN (Dr. Isaacs, Dr. Sartor, and Dr. Jain)
    - Laurie Powers, RN (Dr. Herfarth, Dr. Hansen)

† Baseline echocardiogram with ejection fraction documentation and cardiology consultation are needed prior to initiation of anti-TNF therapy. In this situation, should avoid high doses of anti-TNF therapy and provide close follow-up with prompt discontinuation of anti-TNF-alpha therapy if HF worsens

‡ Can only be used under the discretion of treating neurologist.

- Christina Womble, RN (Dr. Long, Dr. Sheikh)

- Patient's teaching/training in subcutaneous injection technique

- Pre-treatment laboratory evaluation:
  1. Screen for latent Tuberculosis (Quantiferon gold TB test or Tuberculin skin test + chest X-ray)[§]
  2. Screen for chronic infections (HBs-Ag, HBs-Ab, HBc-Ab, HCV Ab, HIV testing)
  3. Baseline LFTs, albumin, CBC, renal function and CRP

Therapy administration:

- To ensure proper use, allow the prefilled syringe or autoinjector to sit at room temperature outside the carton for 30 minutes prior to subcutaneous injection. Do not warm SIMPONI in any other way.

- Prior to administration, visually inspect the solution for particles and discoloration through the viewing window. SIMPONI is clear to slightly opalescent and colorless to light yellow. Do not use SIMPONI, if the solution is discolored, or cloudy, or if foreign particles are present.

- Do not use any leftover product remaining in the prefilled syringe or prefilled autoinjector.

- At the time of dosing, if multiple injections are required, administer the injections at different sites on the body.

- Rotate injection sites and never give injections into areas where the skin is tender, bruised, red, or hard.

[§] Tuberculosis testing and anti-TNF therapy:
- Tuberculin skin test (TST) can be falsely negative in patients with (1) severe malnutrition and (2) receiving immunosuppressive drug (corticosteroids, anti-TNF therapy, and chemotherapy).
- Neither Quantiferon gold TB test nor TST can provide 100% sensitivity for detecting latent TB.
- **In patients at high risk for TB, both tests should be considered with treatment if either one is positive.**
- In patients with latent TB, anti-TNF therapy can be started after 4 weeks of TB therapy. In patients with active TB, anti-TNF therapy should be delayed until completion of TB therapy is possible.

- Patients sensitive to latex should be instructed not to handle the needle cover on the prefilled syringe or the needle cover of the prefilled syringe within the autoinjector cap because it contains dry natural rubber (derivative of latex).

Laboratory monitoring while on therapy:

- CBC with differential, ALT, and creatinine every 3 months
- CRP if clinically indicated
- Periodic TB testing**

Special Considerations

- Golimumab is pregnancy Category B and should be continued during pregnancy. It can cross the placenta during the third trimester and therefore live or live-attenuated vaccines should not be given to the infant born to mother receiving adalimumab within the first 6 months of life.

- The limited data available suggests that anti-TNF therapies are compatible with breastfeeding and therefore the anti-TNF therapy should not influence the decision to breast-feed, and breast-feeding should not influence the decision to use these medications

- Live vaccines are contraindicated if patient receiving anti-TNF agents or planning to initiate therapy within 4-6 weeks

- Patients should be advised to comply with general cancer screening protocols: mammograms, annual pap smears, CRC/dysplasia surveillance

- Protect against UV radiation (sunscreen) and annual dermatological screening

**Patients should be assessed for risk of TB exposure at each clinic visit with repeat testing based on the risk. Patients at high risk include: 1. Exposure to patients with active TB, 2. History of travel to high-risk countries- Mexico, Philippines, Vietnam, India, China, Haiti, and Guatemala. For complete list of high risk countries visit: http://www.stoptb.org/countries/tbdata.asp .3. Patients who live or work in a high-risk environment- homeless shelter, prison or jail, or long-term care facility, and 4. Health-care workers.

References:

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5. Lichtenstein, GR. "Management of Crohn's disease in adults." *Am J Gastroenterol*, 2009: 465-83.
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7. Mowat, C. "Guidelines for the management of inflammatory bowel disease in adults." *Gut*, 2011: 571-607.
8. Sandborn, W.J. "Subcutaneous golimumab induces clinical response and remission in patients with moderate-to-severe ulcerative colitis." *Gastroenterology* , 2014: 85-95.
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