UNC
SCHOOL OF MEDICINE
DEPARTMENT OF MEDICINE
Division of Gastroenterology
and Hepatology

UNC Inflammatory Bowel Disease Drug Protocol

Humira: HUMIRA (adalimumab) is a medicine called a TNF *blocker,* that is a type of protein that blocks the action of a substance your body makes called TNF-alpha. This class of drugs has been shown to be effective in treating certain inflammatory diseases such as rheumatoid arthritis and Crohn's disease. It has similar activity to REMICADE but is a different protein. It is currently in clinical trials for Crohn's disease. It is FDA approved for the treatment of rheumatoid arthritis.

Current Indications for Humira at UNC (February 2005)

- Patients who have had an initial response to Remicade then lose response despite dose escalation
- Patients who have had a delayed infusion reaction to Remicade ("serum sickness" like

It is not used in patients who develop arthritis/arthralgia to Remicade with serologic evidence of drug induced lupus

Treatment Regimen

1. TB skin test and chest X-ray if indicated all patients prior to starting Humira
2. Humira is available in pre-filled syringes 40mg/0.8ml – 2 syringes per box
3. Patient receives an initial 80 mg loading dose (2 syringes) subcutaneously
4. First dose is given in the office to assure proper injection technique. Instruct patient on how to give a subcutaneous injection.
5. Patient then receives 40 mg every other week which can be dose escalated to 80 mg every other week or 40 mg weekly. Dose escalation needs are common in Crohn's disease in which patients often require a higher dose than the RA population.
6. Rarely patients may need 80 mg per week – however this may be cost prohibitive.

References:

1. Barthel, HR, Gille, T, Halbsguth, A and Kramer, M Successful treatment with adalimumab in infliximab resistant Crohn's disease J Gastroenterol and Hepatol (2005) 20, 14641473

2. Vesga L, Terdiman JP, Mahadevan U. Adalimumab use in pregnancy. Gut. 2005 Jun;54(6):890.

3. Papadakis KA, Shaye OA, Vasiliauskas EA, Ippoliti A, Dubinsky MC, Birt J, Paavola J, Lee SK, Price J, Targan SR, Abreu MT. Safety and efficacy of adalimumab (D2E7) in Crohn's disease patients with an attenuated response to infliximab. Am J Gastroenterol. 2005 Jan;100(1):75-9.

4. Sandborn, W, Hanauer, SB, Lukas, M, Wolf, D, Isaacs, K, MacIntosh, DG, Panaccione, R, Rutgeerts, P, Pollack, PF Maintenance of remission over 1 year in patients with active Crohn's disease treated with adalimumab: Results of a blinded placebo-controlled study Am. J. Gastroenterol. (2005) 100:S311

5. Sandborn, W, Hanauer, SB, Lukas, M, Wolf, D, Isaacs, K, MacIntosh, DG, Panaccione, R, Rutgeerts, P, Pollack, PF Remission and clinical response induced and maintained in patients with active Crohn's disease treated for 1-year open-label with adalimumab Am. J. Gastroenterol. (2005) 100:S316

6. Sandborn, W, Hanauer, S, Lukas, M, Wolf, D, Isaacs, K, MacIntosh, D., Panaccione, R., Rutgeerts, P and Pollack, P (2005) Induction and maintenance of clinical remission and response in subjects with Crohn's disease treated during a 6-month open-label period with fully human Anti-TNFalpha monoclonal antibody Adalimumab (humira) *Gastroenterology*128:A111

UNC SCHOOL OF MEDICINE
DEPARTMENT OF MEDICINE
Division of Gastroenterology and Hepatology

Patient Safety Sheet: Humira (Adalimumab) from www.humira.com

Do not start taking Humira

- If you are allergic to the drug or anything in it.

You should not start taking Humira:

- If you have any type of infection An infection can be in one part of your body, such as an open sore, or it can be an illness such as the flu.

Tell your doctor:

- If you have had if you have had any infection in the past that keeps coming back, or if you have any problems that increase the risk of infections,
- if you feel any numbness or tingling,
- if you have ever had a disease that affects your nervous system such as multiple sclerosis, or
- if you have ever been treated for heart failure.

Before you take HUMIRA, your doctor should test you for tuberculosis, or TB. Tell your doctor if you have ever had TB, or been near someone who had TB.
Signs of TB include

- a dry cough that doesn't go away
- weight loss
- fever
- night sweats

If these or any other signs of infection appear after you take HUMIRA, tell your doctor right away.

Also tell your doctor:

- about all the medicines you are taking or considering taking – the combination of HUMIRA and Kindred (anaconda) is not recommended
- before you receive any vaccines
- if you are pregnant, become pregnant or plan to become pregnant

Once you start taking HUMIRA, tell your doctor right away or seek emergency care immediately if you have an allergic reaction such as a bad rash, swollen face, or trouble breathing. Tell your doctor right away if you have signs of a blood disorder such as persistent fever, bruising, bleeding or paleness. There have been rare cases of severe allergic reactions after taking HUMIRA. There have also been rare cases of serious and sometimes fatal infections. Lymphoma, rare cases of nervous system disorders, and serious blood disorders have occurred in patients taking drugs called TNF blockers such as HUMIRA.

The most common side effects of HUMIRA are:

- injection site reactions
- upper respiratory and sinus infections
- headache
- rash
- injection site pain