



INFORMED CONSENT FOR TREATMENT WITH TUMOR NECROSIS FACTOR (TNF) BLOCKERS

Enbrel

Humira

Remicade

Simponi

Cimzia Inflectra

Avsola

TNF blockers have been approved by the Food and Drug Administration (FDA) for the treatment of a variety of different conditions including Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis.

TNF blockers can help reduce joint damage and the signs and symptoms of these diseases.

People with these diseases have too much of a protein called tumor necrosis factor (TNF), which is made by your immune system.

TNF blockers can reduce the effect of TNF in the body and block the damage that too much TNF can cause, but it can also lower the ability of your immune system to fight infections.

WARNINGS:

TNF blockers decrease immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Death from serious infections has been reported in patients receiving TNF blockers.

Before starting treatment with a TNF blocker, you should have a tuberculosis test done to check for tuberculosis that may not be causing any symptoms (latent tuberculosis). If you have been diagnosed with tuberculosis, anti-tuberculosis medicines must be started before you start a TNF blocker. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis, or have come into contact with someone with tuberculosis. Tell your doctor if you have ever had a positive PPD (tuberculosis skin test) or a positive tuberculosis blood test as this may require treatment.

You should tell your doctor if you have ever lived in the southwestern United States as you may have been exposed to a common infection present in those regions. This infection may not cause symptoms until your immune system is suppressed on a TNF blocker. Your doctor may decide to test you for this infection.

Tell your doctor immediately if you have any complaints that may indicate an infection. These include but are not limited to pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, flu like symptoms, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus.

Tell your doctor if you have been diagnosed as having an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive TNF blockers while you have an infection or while you are on antibiotics. TNF blockers can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop your TNF blocker temporarily around the time of your surgery.

PRECAUTIONS:

Infections. TNF blockers can make you more likely to get infections or make any infection that you have worse. Call your doctor right away if you have any symptoms of infection.

Cancer. People with rheumatoid arthritis, especially those with chronic or very active disease may be more likely to get lymphoma (lymph node cancer). TNF blockers may increase the risk of cancer. TNF blockers have been shown to increase the risk of non-melanoma skin cancer. You should see a skin specialist to screen for skin cancer.

Previous Hepatitis B infection. If you have been previously infected with the hepatitis B virus (a virus that affects the liver), the virus can become active while you are on a TNF blocker. You will be screened for hepatitis B before starting a TNF blocker.

Nervous System Problems. Rarely, people who use TNF blockers have developed nervous system problems such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your doctor right away if you get any of these symptoms: numbness or tingling in any part of your body, vision changes, weakness in your arms or legs, dizziness.

Blood problems. Low blood counts have been seen with TNF blockers. Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding very easily, or looking pale. Your doctor will periodically order labs to check on your blood count.

Heart failure. New or worsening heart failure can happen in people who use TNF blockers. If you have heart failure your condition should be watched closely. Call your doctor if you get new or worsening symptoms of heart failure, such as shortness of breath or swelling of your lower legs or feet.

Psoriasis. Some people using TNF blockers develop psoriasis or worsening of psoriasis that they already have. Tell your doctor if you develop skin rashes.

Allergic reactions. Call your doctor if you have any symptoms of an allergic reaction such as severe rash, swollen face or trouble breathing.

Autoimmune reactions:

Lupus like syndrome. Symptoms include a rash on your body that gets worse in the sun. Symptoms go away when you stop using the TNF blocker.

Autoimmune hepatitis. Liver problems can happen in people using TNF blockers. These problems can lead to liver failure and death. Your doctor will periodically order lab tests to check on your liver function.

Pregnancy and breast feeding. It is not known if TNF blockers can cause fetal harm when given during pregnancy, or if it is safe to receive TNF blockers while breast feeding.

Vaccines. You should not receive live vaccines while on a TNF blocker, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered while on a TNF blocker. The nasal spray version of the flu vaccine is a live vaccine and should not be administered while on a TNF blocker. Please inform your doctor if someone in your household has received or will receive a live virus vaccine.

SIDE EFFECTS:

Injection Site reactions (for TNF blockers that are self-injected) such as redness, swelling, itching or pain. These symptoms usually go away within a few days or weeks. If you have pain, redness or swelling around the injection site that does not go away or gets worse, call your doctor.
Infusion reactions (for TNF blockers that are infused) such as headache, rash, itching, low blood pressure. Tell your infusion nurse if you are experiencing any symptoms during your infusion. Call your doctor if you have any symptoms after your infusion.

Upper respiratory infections such as sinusitis. These typically do not need treatment with antibiotics.

These are not all the side effects with TNF blockers. Tell your doctor about any side effect that bothers you or does not go away.

MEDICATION ADMINISTRATION:

Enbrel. The most common dose is 50 mg self-injected under the skin once every 7 days.

Humira. The most common dose is 40 mg self-injected under the skin once every 14 days.

Remicade/Inflectra/ Avsola. The dose and frequency depend on your diagnosis and how you are doing. When starting Remicade, infusions are given at 0, 2 and 6 weeks (i.e., 3 infusions over the first 6 weeks), and then usually every 6 or 8 weeks. Infusions typically last about 2 hours.

Simponi. Simponi is available as either a self-injection or an intravenous (IV) drug.

- **Self-injection.** 50 mg once every 4 weeks.
- **IV.** 2 mg/kg at 0 & 4 weeks (i.e., 2 infusions over the first month), and then every 8 weeks. Infusions typically last about 30 minutes.

Cimzia. The most common dose is 400 mg self-injected initially, and then repeated at 2 and 4 weeks. Then the dose is either 200 mg every 14 days or 400 mg every 4 weeks.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive a TNF blocker. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a copy of this form for my records.

Our office will contact your insurance company and the necessary arrangements will be made for approval of the medication and administration. **Our office does not provide a guarantee of coverage for services. If coverage is not provided, you will be responsible for any charges incurred for treatment and/or follow up care.**

Patient signature

DOB

Date