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INFORMED CONSENT FOR TREATMENT WITH CIMZIA

Cimzia has been approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid Arthritis.

Cimzia blocks the action of a protein called Tumor Necrosis Factor (TNF). This blockade results in decreased joint swelling and pain (inflammation)

WARNINGS:

Cimzia decreases immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Deaths from serious infections have been reported in patients receiving Cimzia.

Before starting CIMZIA, tell your doctor if you:

- think you have an infection.
- are being treated for an infection
- have signs of an infection, such as a fever, cough, flu-like symptoms
- have any open cuts or sores on your body
- get a lot of infections or have infections that keep coming back
- have diabetes
- have HIV
- have tuberculosis (TB), or have been in close contact with someone with TB
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take CIMZIA. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B

Before starting treatment with Cimzia your doctor will arrange for you to have a tuberculosis skin 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 Cimzia therapy. This will reduce the likelihood of a serious tuberculosis infection.

Tell your doctor if you have been diagnosed as having an infection, are on antibiotics or if you are prone to recurrent infections. 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, 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.

You should not receive Cimzia while you have an infection or while you are on antibiotics.

Cimzia 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 Cimzia temporarily around the time of your surgery.

PRECAUTIONS:

Serious side effects have happened in patients taking CIMZIA including:

- **Certain Types of Cancer** .There have been cases of certain types of cancer in people taking CIMZIA or other TNF blockers. People with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- **Heart Failure** including new heart failure or worsening of heart failure you already have. Symptoms include shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- **Nervous System Problems** such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Symptoms include dizziness, numbness or tingling, problems with your vision, and
- weakness in your arms or legs.
- **Allergic Reactions.** Signs of an allergic reaction include a skin rash, swelling of the face, tongue, lips, or throat, or trouble breathing.
- **Hepatitis B virus reactivation in patients who carry the virus in their blood.** In some cases
- patients have died as a result of hepatitis B virus being reactivated after treatment with Cimzia. Your doctor should monitor you carefully during treatment with CIMZIA if you carry the hepatitis B virus in your blood.
- **Lupus-like syndrome:** Treatment with Cimzia may result in the formation of autoimmune antibodies and, rarely, may cause a lupus-like syndrome. In clinical trials, patients who developed a lupus-like syndrome have had resolution of the syndrome after treatment with Cimzia was stopped.
- **Cimzia has been reported to cause liver test abnormalities and blood cell count abnormalities.** The blood cell count abnormalities can be severe. You should let your doctor know if you notice bruising, bleeding or paleness of the skin.
- **Vaccinations.** You should not receive live vaccines (for eg. polio, smallpox) while on Cimzia, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered while on Cimzia. The nasal spray version of the flu vaccine is a live vaccine and should not be administered while on Cimzia. Please let your doctor know if someone in your household has received or will receive a live virus vaccine.
- **Pregnancy and Breastfeeding:** Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. CIMZIA has not been studied in pregnant or nursing women.
- **Medication Interactions:** Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking CIMZIA. Especially, tell your doctor if you take Kineret (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or

Tysabri® (natalizumab). You have a higher chance for serious infections when taking CIMZIA with Kineret®, Oencia®, Rituxan®, or Tysabri®.

- You should not take CIMZIA while you take one of these medicines: Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept).

ADVERSE REACTIONS:

The most common side effect from Cimzia is a reaction at the site of the injection. You may experience some redness, itching or hives. If a reaction occurs it is usually mild and goes away after a few weeks of continued usage of the drug.

MEDICATION ADMINISTRATION:

Cimzia comes in a prefilled syringe that you inject under the skin. You will be taught how to do the injections. Cimzia is dosed as follows:

Initially and at weeks 2 and 4 you will administer 2 syringes (400 mg) of Cimzia
Thereafter you will administer 1 syringe (200 mg) every 2 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 and self-administer Cimzia. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

Patient signature

Date

Witness signature

Date