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Informed Consent for Treatment with Remicade/Inflectra

Remicade (Infliximab) and Inflectra has been approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis and Psoriasis. Remicade and Inflectra block the action of a protein called Tumor Necrosis Factor (TNF). This blockade results in decreased swelling (inflammation) and decreased immune function (immunosuppression).

WARNINGS:

Remicade and Inflectra 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 have been reported in patients receiving Remicade.

Before starting treatment with Remicade/Inflectra, you should have a tuberculosis skin or blood 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 Remicade/Inflectra therapy. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you have ever had tuberculosis or have met someone with tuberculosis. Tell your doctor if you have ever had a positive PPD (tuberculosis skin test) or blood test – which may require treatment.

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.

Tell your doctor if you have been diagnosed with an infection or if you are prone to recurrent infections. You should not receive Remicade/Inflectra if you have an infection. You can receive Remicade/Inflectra once your infection has been treated.

Tell your doctor if you are on antibiotics around the time that your infusion is due.

Tell your doctor if you have planned surgery, as the timing of the surgery may need to be adjusted in accordance to your infusion.

PRECAUTIONS:

Treatment with Remicade/Inflectra 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 Remicade was stopped.

Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to developing cancer, particularly lymphoma. The impact of Remicade/Inflectra on this is not known. Possible long-term side effects such as the development of lymphoma or other cancers cannot be predicted.

Treatment with Remicade/Inflectra can be associated with the formation of antibodies to the drug. Patients who develop antibodies are more likely to have an infusion reaction. Formation of antibodies is lowered, and fewer infusion reactions occur if methotrexate is taken along with Remicade.

It is not known if Remicade/Inflectra can cause fetal harm when given during pregnancy, or if it is safe to receive Remicade/Inflectra while breast feeding

Remicade may worsen congestive heart failure. Some deaths have occurred in patients with congestive heart failure. Tell your doctor if you have been diagnosed with congestive heart failure.

There have been rare reports of severe liver abnormalities in patients receiving Remicade, some of which have been fatal. Your liver functions will be routinely monitored.

Remicade has been reported to cause 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.

Remicade may cause worsening of psoriasis or the development of psoriasis.

There are rare reports of Remicade causing damage to the nervous system, for eg. seizures, numbness, tingling, paralysis. Let your doctor know if you develop any such complaints.

You should not receive live vaccines (for eg. polio, smallpox) while on Remicade/Inflectra, without speaking with your doctor. The injectable flu vaccine and pneumonia vaccine can be safely administered while on Remicade/Inflectra. The flu vaccine in the form of nasal spray is a live vaccine and should not be administered while on Remicade/Inflectra. Please let your doctor know if someone in your household has received or will receive a live virus vaccine.

ADVERSE REACTIONS:

Infusion related reactions have occurred in about 16% of patients treated with Remicade in clinical trials.

These reactions may cause fever, chills, itching, rash, hives, chest pain, low blood pressure, high blood pressure, difficulty breathing, increased heart rate, muscle pain, anxiety, difficult sleeping, dizziness, depression, fatigue, flu like syndrome, upper respiratory tract infection, sinusitis, laryngitis, urinary tract infection, headache, sweating, nausea, diarrhea, abdominal pain, abnormal liver enzymes, abnormal blood counts, thrush, numbness, tingling, joint pain and back pain.

All patients recovered with treatment, and/or with slowing down or stopping the infusion.

MEDICATION ADMINISTRATION:

Remicade/Inflectra is administered as a single intravenous infusion lasting at least 2 hours. You will be at the office for at least 3 hours, possibly longer. You will see your physician in follow-up to monitor your progress and response to the Remicade/Inflectra. Also, please call us if you experience any side effects and we may give you additional medication to take before the infusion to reduce the risk of side effects. If you receive these medications, you may need someone to drive you home after the infusion.

EMERGENCY CONTACTS:

In case of an emergency, please call 911 or go to the nearest emergency room. You can contact our office at (916) 677-4744 from 8:00 am to 5:00 pm Monday – Friday.

I certify that I have read and understand this consent form and agree to receive Remicade/Inflectra intravenous treatment. 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 Name Patient DOB

_____ _____

Patient Signature Date

FINANCIAL RESPONSIBILITY:

Our office will contact your insurance company, and the necessary arrangements will be made for approval of the medication and administration. You may want to follow up with your insurance company also to be sure everything is covered. **Our office does NOT provide a guarantee of coverage for any of these services. If coverage is not provided, YOU WILL BE RESPONSIBLE for any charges incurred for treatment and/or follow-up care.**

_____ _____

Patient signature Date