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Informed Consent for Treatment with Rituxan

Rituximab is a monoclonal antibody that was approved in 1997 for the treatment of lymphoma (lymph node cancer) by the Food and Drug Administration (FDA). It is estimated that over 500,000 patients with lymphoma have been treated with rituximab since that time.
In 2006, the FDA approved rituximab in combination with methotrexate to reduce signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies (such as enbrel, humira and remicade).

HOW RITUXIMAB WORKS:

B cells are a type of cell in your body that are felt to play a role in the inflammation that results in joint pain and swelling in rheumatoid arthritis.
Rituximab is a protein that fits like a lock and key with a protein on certain B cells in your body. Once rituximab attaches to these B cells, it affects their ability to function normally, and therefore may decrease joint pain and swelling in rheumatoid arthritis.

WARNINGS:

Fatal infusion reactions have been reported in rare patients who received rituximab for the treatment of lymphoma.
Severe skin and kidney damage has also been reported in patients who have received rituximab for the treatment of lymphoma. Rare cases of death from these reactions have been reported.

SIDE EFFECTS:

Infusion related side effects occur in about one third of patients. These side effects usually occur within 30 minutes to 2 hours of starting the infusion. It may be necessary to slow down or interrupt your infusion, but the infusion can usually be restarted once symptoms resolve.
Infusion reactions can include but are not limited to fevers, chills, shakes, swelling of the face or throat, drop in blood pressure, shortness of breath and high blood pressure. Nausea and vomiting, itching, fatigue, headache, throat irritation, hives, rash, runny nose, muscle pain and dizziness have also been reported.

Serious infections may occur. 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 as having an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive rituximab while you have an infection or while you are on antibiotics.

Tell your doctor if you have a planned surgery. You should not receive rituximab around the time of a planned surgery.

Other reported events that have occurred in patients with lymphoma who have received rituximab include but are not limited to:
Reactivation of hepatitis B, abnormalities in blood counts, heart and lung abnormalities, autoimmune events, and rare cases of a serious neurological condition (progressive multifocal leukoencephalopathy).
Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to develop cancer, in particular lymphoma. The impact of rituximab on this is unknown.
It is not known if rituximab can cause fetal harm when given during pregnancy, or if it is safe to receive rituximab while breast feeding. It is not known if rituximab can affect fertility.
You should not receive live vaccines (for eg. polio, smallpox) without speaking with your doctor. The injected flu vaccine and pneumonia vaccine can be safely administered. The nasal spray version of the flu vaccine is a live vaccine and should not be administered.
Other side effects not listed above can also occur in some patients. Tell your doctor if you develop any problems.

Your first infusion may take most of the day. The second infusion will usually require less time. You should arrange for someone to be available to drive you home after your infusion in case this is needed.
You will be receiving pre-medication that may cause your blood sugar to rise temporarily. If you are diabetic PLEASE discuss this with your rheumatologist.

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.

Enbrel and Humira are also approved by the FDA for the treatment of Rheumatoid Arthritis. These drugs are self injected and do not require an intravenous infusion. I certify that my rheumatologist has discussed the use of these drugs as an alternative to Rituximab with me.

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

_____ _____

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