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Informed Consent for Treatment with Orencia

Orencia (Abatacept) is a medicine that is used to treat adults with moderate to severe Rheumatoid Arthritis (RA). A healthy and normal immune system defends the body against infections caused by bacteria and viruses. In people with RA, the immune system attacks normal body tissues causing damage and inflammation especially in the tissues of your joints. Orencia interferes by decreasing the immune system's attack on normal tissues, which can lead to less pain and inflammation, and slow the damage to your bones and cartilage.

WARNINGS:

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

Before starting treatment with Orencia, you should have tuberculosis or blood test done 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 Orencia therapy. This will reduce the likelihood of a serious tuberculosis infection. Tell your doctor if you 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 – this 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 Orencia if you have an infection. You can receive Orencia once your infection has been treated.

Tell your doctor or infusion nurse 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 with your infusion.

PRECAUTIONS:

Patients with a long duration of inflammation and chronic exposure to immunosuppressant treatments are more prone to developing cancer, particularly lymphoma. There have been rare cases of certain kinds of cancer in patients receiving Orencia. The role of Orencia in the development of cancer is not known.
Orencia has not been studied in pregnant women or nursing mothers, so it is not known what the effects are on pregnant women or nursing babies. The safest approach at this time is to not use Orencia if you are pregnant, breast feeding, become pregnant, or are thinking about becoming pregnant.
You should not receive live vaccines (for eg. polio, smallpox) while on Orencia or within 3 months of having received Orencia. The injectable flu vaccine and pneumonia vaccine can be safely administered while on Orencia. The flu vaccine

in the form of nasal spray is a live vaccine and should not be administered while on Orencia. Orencia may blunt the effectiveness of some vaccines. No data is available on the transmission of infection from persons receiving live vaccines to persons receiving Orencia. 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 9% of patients treated with Orencia in clinical trials.
These reactions include but are not limited to headache, high blood pressure, dizziness, low blood pressure, shortness of breath, nausea, flushing, hives, cough, hypersensitivity, itching, rash, wheezing, and rarely anaphylaxis. Most of these reactions were mild to moderate, and responded to appropriate treatment, or to slowing down or stopping the infusion.

Injection site reactions can occur resulting in redness or itching at the site of the injection.

Patients with COPD (chronic obstructive pulmonary disease) developed adverse events more frequently. These adverse events included COPD exacerbation, cough, wheezing, and shortness of breath. Tell your doctor if you have COPD or if your breathing worsens in any way.

MEDICATION ADMINISTRATION:

Orencia is administered as a single intravenous infusion lasting about 30 minutes. You will receive your first dose of Orencia followed by additional doses at 2 and 4 weeks after the first dose. You will then receive a dose every 4 weeks. You will see your physician in follow-up to monitor your progress and response to Orencia.

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 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 the Orencia 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