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Informed Consent for Treatment with Benlysta

Benlysta (belimumab) has been approved by the Food and Drug Administration (FDA) for the treatment of active systemic lupus erythematosus (SLE) where the response to standard treatment has been inadequate. It has not been evaluated for the treatment of severe disease with kidney or brain involvement. Benlysta reduces the function of B-cells, a type of white blood cell which is felt to be important in the pathogenesis of lupus.

WARNINGS:

Benlysta decreases immune system function (immunosuppression), which can result in serious infections and possibly death. Before starting Benlysta, tell your doctor if you:

- Have HIV
- Have tuberculosis (TB) or have been in close contact with someone with TB
- Have or have had Hepatitis B or Hepatitis C
- Have or have had any type of cancer

You should notify 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, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increase frequency of urination, vaginal discharge, and cuts or wounds that are red swollen or draining pus. **You should not receive Benlysta while you have an infection or while you are taking antibiotics.** Benlysta can be restarted once you have completed your antibiotic course and your infection has resolved. Tell your doctor if you have planned surgery, as you will need to stop Benlysta temporarily around the time of your surgery.

PRECAUTIONS:

- Serious side effects may occur in patients taking Benlysta including: death, serious infections, allergic reactions, and depression. Patients on this medication should not receive any live vaccines such as the one given for shingles. It should not be given in conjunction with other biologic drugs or cyclophosphamide. Its safety in pregnancy and breast feeding is unknown. Common side effects can include nausea, diarrhea, fever, bronchitis, insomnia, body pain, migraines and sore throat.

MEDICATION ADMINISTRATION:

Benlysta IV is administered as a single intravenous infusion over one hour. Benlysta is given every 2 weeks for the first 3 doses and then monthly. Therefore, you will be in the office at least one hour and possibly longer. You will see your physician in follow up to monitor your progress and response to Benlysta. Also, please call if you experience any side effects, and we will be available to you 24 hours a day if you experience any problems.

Benlysta SC is given weekly

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 Benlysta 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 signature DOB

_____

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 DOB

_____

Date