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Informed Consent for Treatment with Stelara or Tremfya

Stelara (Ustekinumab) and Tremfya (Guselkumab) have been approved by the Food and Drug Administration for the treatment of Psoriatic Arthritis and Psoriasis.
MECHANISM – These are antibodies directed against IL-23 that causes or perpetuate inflammation.

WARNINGS and PRECAUTIONS:

- These medications decrease immune function. Hence, they increase the risk of infections including fungal, viral and serious bacterial infections, some requiring hospitalization. Death from serious infections has been reported. Tell your doctor if you have an infection or if you are prone to recurrent infections.
- You should not receive these medications if you have an infection, but you may be able to restart treatment once the infection has been treated.
- Before starting treatment with these medications, you should get tested for tuberculosis, hepatitis B and hepatitis C.
- Patients on these medications should not receive live vaccines. You can still receive killed vaccines.
- Tell your doctor if you are planning to have a surgery or if you are on antibiotics at the time your next injection is due. The timing of the surgery may need to be adjusted.
- Tell your doctor if you have had any types of cancer, including skin cancers. The safety of these medications in patients with a history of cancer has not been evaluated.
- RPLS (reversible posterior leukoencephalopathy syndrome) is a rare condition that affects the brain and can cause death. If found early and treated most people recover. Tell your doctor if you have: headache, seizures, confusion, or vision problems.
- There is no information on using this medication in pregnancy or nursing, and use of these medications in nursing mothers or pregnancy should be first discussed with your doctor.

ADVERSE REACTIONS:

- These medications are given by injection under the skin. Itching or redness at the site of injection or serious allergic reactions can occur. Symptoms may include: feeling faint, swelling of your face, eyelids, tongue, or throat, trouble breathing, throat tightness, chest tightness or skin rash.
- Increased frequency of infections including upper respiratory infections, urine infections etc; headache, fatigue, diarrhea, back pain, dizziness, throat pain, itching, muscle ache, depression. These occurred at a rate of 1% to 8% and were no different with either the 45 mg or the 90 mg dose.
- Occasionally rise in liver enzymes, and lowering of cell counts can occur. Regular blood testing is necessary. These reverse upon stopping the medication. Need for continuation or stopping the medicine should be determined in consultation with your doctor.

MEDICATION ADMINISTRATION:
The medication is given in the office by the medical assistant by subcutaneous (under the skin) injection. Dosing frequency varies and will be determined by your physician.

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 these medications injections. I have had an opportunity to discuss this treatment with my physician and ask questions regarding risks and alternatives. I will be given a signed copy of this form for my records.

_____ _____
Patient Signature Date