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INFORMED CONSENT FOR TREATMENT WITH ACTEMRA or KEVZARA

Actemra and Kevzara have been approved by the Food and Drug Administration (FDA) for the treatment of moderately to severely active Rheumatoid Arthritis (RA) in those who have had an inadequate response to one or more TNF blocker treatments.
Actemra and Kevzara block the action of a protein called Interleukin-6. This blockade results in decreased joint pain and swelling (inflammation).

WARNINGS:

Actemra and Kevzara decrease immune system function (immunosuppression), which can result in serious infections including invasive fungal infections or worsening of an existing infection. Deaths from serious infections have been reported in patients receiving these medications
Before starting Actemra or Kevzara, tell your doctor if you:

- have HIV
- have tuberculosis (TB), or have been in close contact with someone with TB
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take Actemra or Kevzara. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B

Before starting treatment with Actemra or Kevzara your doctor will arrange for you to have a tuberculosis skin 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 therapy. This will reduce the likelihood of a serious tuberculosis infection. You also will be tested for Hepatitis B.

Tell 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, 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. **You should not receive Actemra or Kevzara while you have an infection or while you are on antibiotics.** The medication can be restarted once you have completed your antibiotic course and your infection has resolved.

Tell your doctor if you have a planned surgery, as you will need to stop Actemra and Kevzara temporarily around the time of your surgery.

PRECAUTIONS:

Serious side effects have happened in patients taking Actemra and Kevzara including:

- **Certain Types of Cancers -** There have been cases of certain types of cancer in people taking Actemra or Kevzara. People with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- **Gastrointestinal perforations** have been reported in clinical trials usually in people with diverticulitis. Tell your doctor if you have been diagnosed with diverticulitis.
- **Nervous System Problems** such as multiple sclerosis may occur. Symptoms may include dizziness, numbness or tingling, problems with your vision, and weakness in your arms or legs.
- **Infusion/Allergic Reactions.** The most common reactions are high blood pressure, headache and skin reactions. Serious allergic reactions may occur. Death from a suspected severe allergic reaction has been reported.
- **Cholesterol levels** may be elevated by Actemra or Kevzara and should be monitored.
- Hepatitis B virus reactivation in patients who carry the virus in their blood.
- **Liver test and blood cell count abnormalities.** Serious cases of liver damage have occurred. Let your doctor know if you notice bruising, bleeding, paleness or yellowness of the skin.

Vaccinations. You should not receive live vaccines (for eg. polio, smallpox, the Zostavax for Shingles) while on Actemra or Kevzara, without speaking with your doctor. The injected flu vaccine and pneumonia vaccine and injectable killed Shingles vaccine can be safely administered while on Actemra and Kevzara. The nasal spray version of the flu vaccine (which is a live vaccine) or live shingles vaccine should **not** be administered while on Actemra or Kevzara. Please let your doctor know if someone in your household has received or will receive a live virus vaccine.

Pregnancy and Breastfeeding: Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. Neither Actemra, nor Kevzara have been studied in pregnant or nursing women.

Medication Interactions: Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking Actemra or Kevzara.

You should not take Actemra or Kevzara while you are taking any other biologic medication – these include Enbrel, Humira, Remicade, Kineret, Orencia and Rituxan. Actemra and Kevzara should not be taken with other biologic medications.

ADVERSE REACTIONS:

The most common side effects from Actemra and Kevzara are respiratory infections, headache, high blood pressure and abnormal liver function tests.
Injection site reactions can occur with subcutaneous Actemra and Kevzara.

MEDICATION ADMINISTRATION:

Actemra can be given as a self-administered weekly or biweekly subcutaneous injection, or as a monthly intravenous infusion lasting approximately one hour. Kevzara is self-administered once every two weeks. You will see your physician in follow-up to monitor your progress and response to the medication. Also, please call us if you experience any side effects, and we will be available to you 24 hours a day if you experience any problems.

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 Actemra intravenous infusions or to self-administer subcutaneous Actemra or Kevzara. 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