Patient Consent for Treatment Form

NAME OF DRUG: Baricitinib

SITE OF TREATMENT: Central Maine Healthcare (CMMC,BH,RH)

PHONE NUMBER: 207-795-2200

Your doctor has recommended you be treated with baricitinib. You have the option to be treated with this medication. Before you decide whether you would like to be treated with this medication, your medical provider would like you to review this information. If you decide that you would like to receive this treatment, you will be asked to sign this form. A copy of this form and an FDA approved fact sheet will be given to you for your reference.

What is baricitinib?

Baricitinib is a prescription medicine that is FDA approved to treat adult patients with moderate to severe active rheumatoid arthritis. Baricitinib is prescribed after treatment with at least one other medicine called a Tumor Necrosis Factor (TNF) antagonist. Baricitinb is prescribed if a TNF has been used and did not work well enough or could not be tolerated.

Baricitinib is not FDA-approved to treat COVID-19.

Baricitinib is being studied for the treatment of certain people in the hospital with COVID-19. Baricitinib is an investigational medicine when used to treat COVID-19. There is limited information about the safety and effectiveness of using baricitinib to treat people in the hospital with COVID-19.

The FDA has authorized the emergency use of baricitinib for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section of the Fact Sheet for Patients, Parents and Caregivers that you have received.

Baricitinib is an investigational medicine taken by mouth (with or without food). You will receive one dose of baricitinib each day for 14 days or until you are discharged from the hospital (whichever comes first), as instructed by your healthcare provider. If you are unable to swallow whole tablets, your healthcare provider may determine that you can receive baricitinib by gastrostomy tube (G tube) or nasogastric tube (NG tube).

What are the important possible side effects of baricitinib?
Possible side effects of baricitinib are:

- Serious infections. Baricitinib is a medicine that affects your immune system. Baricitinib can lower the ability of your immune system to fight infections other than COVID-19.
- Blood clots. Blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) can happen in some people taking baricitinib. This may be life threatening and cause death.

- Changes in certain laboratory test results. Baricitnib may have an edverse effect on your liver, kidneys or ability to make white blood cells. Your healthcare provider will do blood tests before you start taking baricitinib to check how well your kidney and liver are working, as well as the number of white blood cells that help the body fight infections.
- Allergic reactions. Tell your healthcare provider right away if you have symptoms such as rash, swelling of your lips, tongue, or throat, or hives (raised red patches of skin that are often very itchy). This may mean you are having an allergic reaction.

These are not all the possible side effects of baricitinib. Not a lot of people have been given baricitinib for the treatment of COVID-19. Serious and unexpected side effects may happen. Baricitinib is still being studied for the treatment of COVID-19 so it is possible that all of the risks are not known at this time.

Tell your healthcare provider immediately if you get:

- swelling, pain or tenderness in the leg
- sudden unexplained chest pain
- sudden worsening shortness of breath
- rash, swelling of your lips, tongue, or throat, or hives

RISKS

There are some known risks and adverse reactions to using this medication. You will be provided with the FDA-approved fact sheet that accompanies the emergency use authorization for this medication. You will also be provided with a copy of this consent form. Talk to your healthcare provider about any questions or concerns you have regarding these potential risks or adverse reactions prior to starting this treatment.

MEDICAL HISTORY

You may have a greater chance of experiencing known risks/adverse reactions if you have certain medical problems or conditions. Please tell your healthcare provider about all of your health conditions. In particular, please mention if you have any of the following health problems:

- Have an infection other than COVID-19. You should not take baricitinib if you have an active tuberculosis infection.
- Have hepatitis B, hepatitis C, or HIV.
- Have ever had any type of cancer.
- Have had blood clots.
- Have kidney problems. You should not take baricitinib if you have sudden, severe kidney problems or you are on dialysis.
- Have liver problems.
- Have low red or white blood cell counts.
- Have recently received a vaccine.
- Are pregnant or breastfeeding.
- Are allergic to baricitinib.

OTHER MEDICATIONS

You may have a greater chance of experiencing known risks/adverse reactions if you are taking certain medicines or supplements. Please tell your healthcare provider about all of the medicines you take (including prescription and over-the-counter medicines, vitamins, and herbal supplements). In particular, please mention if you take any of the following medicines:

- Probenecid
- Any medicines that affect your immune system

What other treatment choices are there?

A medicine to treat people in the hospital with COVID-19 has been FDA approved. Like baricitinib, FDA may allow for the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19. Go to:

https://www.covid19treatmentguidelines.nih.gov/

for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19.

Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with baricitinib. Should you decide not to receive it or elect to stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?

Baricitinib has not been studied in pregnant women or breastfeeding mothers. It is not known if baricitinib will harm your unborn baby or if baricitinib passes into your breast milk. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with baricitinib?

Tell your healthcare provider if you have any side effect that bothers you or does not go away. Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Lilly by calling 1-855-LillyC19 (1-855-545-5921). Please notify the healthcare provider at Central Maine Medical Center that gave you this treatment.

How can I learn more?

- Ask your health care provider
- See the Medication Guide for Olumiant® (baricitinib), at http://pi.lilly.com/us/olumiant-us-mg.pdf
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Visit https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Contact your local or state public health department.

COSTS
You may incur the cost of this medication and/or associated procedures if they are not covered by your insurance.

YOUR PERSONAL INFORMATION
Your personal information will be protected under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended from time to time (collectively, HIPAA) as stated in the Central Maine Medical Center Consent, Use and Disclosure Statement. Some of your personal information may be retained in the Clinical Research Department for a limited period of time to optimize your individual care and in accordance with federal regulations. Your information will be made accessible to Eli Lilly and Company as well as the FDA and other regulatory agencies that choose to review it.

PATIENT STATEMENTS

- I have read this consent form, or had it read to me.
- I understand the risks and benefits associated with taking this medication as authorized by the FDA for emergency use and have had the opportunity to ask and have questions answered.
- I would like to pursue treatment for COVID-19 with baricitinib
- I understand that this medication has not been approved to treat COVID-19.
- I will be given a signed copy of this document for my records.
- I have received a copy of the FDA-approved Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Baricitinib
- By signing this form, I am not waiving any of my legal rights.

_____
Patient Name

_____ _____
Patient/ Caregiver/ Legally Authorized Representative Signature Date and Time

Physician Statements:

- I have reviewed the information in this form with the patient (and Legally Authorized Representative, if applicable).
- I have answered the patient's (and Legally Authorized Representative's, if applicable) questions to the best of my ability.

_____
Physician's Printed Name

_____ _____
Physician's Signature Date and Time