Patient Consent for Treatment Form

NAME OF DRUGS: Actemra (Tocilizumab)

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

PHONE NUMBER: 207-795-0111

Your doctor believes it is necessary that you should be treated with Actemra for coronavirus disease 2019 (COVID 19) . You have the option to be treated with this medication, Actemra IV (intravenously, that is, by injection into your vein). 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 ACTEMRA?

ACTEMRA, also known as Tocilizumab, is a FDA-approved prescription medicine that is used to treat adults with moderately to severely active rheumatoid arthritis (RA), after at least one other medicine called a Disease-Modifying Anti-Rheumatic Drug (DMARD) has been used and did not work well, to treat adults with giant cell arteritis (GCA), for slowing the rate of decline in lung function in adults with systemic sclerosis-associated interstitial lung disease (SSc-ILD), and to treat people aged 2 years and older with polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and chimeric antigen receptor (CAR) T-cell induced severe or life-threatening Cytokine Release Syndrome (CRS). ACTEMRA is not FDA- approved to treat COVID-19. ACTEMRA is not authorized for subcutaneous use in people with COVID-19.

There is limited information known about the safety or effectiveness of using ACTEMRA to treat people in the hospital with COVID-19. Available results from clinical trials in adults indicate that treatment with ACTEMRA may decrease the risk of dying in hospitalized patients with COVID-19 who are receiving corticosteroids and who require supplemental oxygen, or a ventilator or ECMO. The safety and effectiveness of ACTEMRA have not been studied in children hospitalized with COVID-19.

The FDA has authorized the emergency use of ACTEMRA for the treatment of COVID-19 in hospitalized adults and children (2 years of age and older) who are receiving corticosteroids and who require supplemental oxygen, or a ventilator or ECMO under an EUA.

How will I receive ACTEMRA?

ACTEMRA is given to you or your child through a vein (intravenous or IV) 1 time as a single dose. If you or your child do not improve after receiving one dose of ACTEMRA, a second dose may be given at least 8 hours after the first dose.

What are the important possible side effects of ACTEMRA?

The most important side effects of ACTEMRA are:

- Serious infections: ACTEMRA is a medicine that affects your or your child's immune system. ACTEMRA can lower the ability of your or your child's immune system to fight infections other than COVID-19. ACTEMRA can make you or your child more likely to get infections or worsen any infection that you or your child have, other than COVID-19.

- Tears (perforation) of the stomach or intestines: Some people taking ACTEMRA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- Liver problems (hepatotoxicity): Some people taking ACTEMRA have experienced serious life-threatening liver problems, which required a liver transplant or led to death.
- Changes in certain laboratory test results: Your or your child's healthcare provider should do blood tests before you or your child start receiving ACTEMRA. You or your child should not receive ACTEMRA if your or your child's neutrophil (white blood cells that help the body fight off bacterial infections) or platelet (blood cells that help with blood clotting and stop bleeding) counts are too low or your or your child's liver function tests are too high.
- Allergic reactions: Tell your or your child's healthcare provider right away if you or your child 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 or your child are having an allergic reaction.
- Nervous system problems: While rare, Multiple Sclerosis has been diagnosed in people who take ACTEMRA. It is not known what effect ACTEMRA may have on some nervous system disorders.
- The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

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 medical 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 medical provider about all of your health conditions. In particular, please mention if you have any of the following health problems:

- Any allergies
- Any serious illnesses particularly infections other than COVID 19, liver problems, stomach-area pain, diverticulitis, stomach ulcers, intestinal ulcers, blood lab abnormalities especially neutrophil and platelet counts or any conditions that affect the nervous system.
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking medications, including prescription, over the counter medications, vitamins, and herbal products

What other treatment choices are there?

Like ACTEMRA, FDA may allow for the emergency use of other medicines 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. Please consult your or your child's healthcare provider on which medicine or combination of medicines might be right for you or your child. Your or

your child's healthcare provider may talk with you about clinical trials you or your child may be eligible for.

It is your choice for you or your child to be treated or not to be treated with ACTEMRA. Should you decide not to receive it or for your child to not receive it, it will not change your or your child's standard medical care

What if I am pregnant or breastfeeding?
There is limited experience giving ACTEMRA to pregnant women or breastfeeding mothers. ACTEMRA may harm your unborn baby. It is unknown if ACTEMRA passes into your breast milk. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

Pregnancy exposure registry
Genentech has a registry for pregnant women who take ACTEMRA. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ACTEMRA, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

How do I report side effects with ACTEMRA?
Contact your or your child's healthcare provider if you or your child have any side effects that bother you or do 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 Genentech, Inc. by calling 1-888-835-2555

How can I learn more?
- Ask your or your child's healthcare provider
- Visit https://www.cdc.gov/COVID19
- 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 Genentech, Inc. 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 Actemra (Tocilizumab)
- 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 Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of ACTEMRA® (tocilizumab) for Coronavirus Disease 2019 (COVID-19)
- By signing this form, I am not waiving any of my legal rights.

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Patient Name Printed

_____ _____

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.

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Physician's Printed Name

_____ _____

Physician's Signature Date and Time