Patient Consent for Treatment Form

NAME OF DRUGS: EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

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

PHONE NUMBER: 207-795-0111

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with EVUSHELD (tixagevimab co-packaged with cilgavimab) for pre-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. 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 COVID-19?
COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.
COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What is EVUSHELD (tixagevimab co-packaged with cilgavimab)?
EVUSHELD is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds [40 kg]) for pre-exposure prophylaxis for prevention of COVID-19 in persons who are:

- not currently infected with SARS-CoV-2 and who have not had recent known close contact with someone who is infected with SARS-CoV-2 **and**
  - o Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
  - o For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (such as severe allergic reaction) to a COVID-19 vaccine(s) or COVID-19 vaccine ingredient(s).

EVUSHELD is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19. EVUSHELD is not authorized for post-exposure prophylaxis for prevention of COVID-19.
The FDA has authorized the emergency use of EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA).

How will I receive EVUSHELD?

- EVUSHELD consists of two investigational medicines, tixagevimab and cilgavimab.
- You will receive 1 dose of EVUSHELD, consisting of 2 separate injections (tixagevimab and cilgavimab).
- EVUSHELD will be given to you by your healthcare provider as 2 intramuscular injections, given one after the other.

You may need to receive additional doses of EVUSHELD for ongoing protection. Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant. The duration that EVUSHELD will protect you from infection may change with certain variants. The best timing for you to receive additional doses of EVUSHELD, if needed, is not known right now, because this depends on which SARS-CoV-2 variants will be present in the future.

What are the important possible side effects of EVUSHELD?

Possible side effects of EVUSHELD are:

- **Allergic reactions**. Allergic reactions can happen during and after injection of EVUSHELD. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe or life threatening.
- **Cardiac (heart) events**: Serious cardiac adverse events have happened, but were not common, in people who received EVUSHELD and also in people who did not receive EVUSHELD in the clinical trial studying pre-exposure prophylaxis for prevention of COVID-19. In people with risk factors for cardiac events (including a history of heart attack), more people who received EVUSHELD experienced serious cardiac events than people who did not receive EVUSHELD. It is not known if these events are related to EVUSHELD or underlying medical conditions. Contact your healthcare provider or get medical help right away if you get any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs .

The side effects of getting any medicine by intramuscular injection may include pain, bruising of the skin, soreness, swelling, and possible bleeding or infection at the injection site.

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

It is possible that EVUSHELD may reduce your body's immune response to a COVID-19 vaccine. If you have received a COVID-19 vaccine, you should wait to receive EVUSHELD until at least 2 weeks after COVID-19 vaccination.

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:

- Have any allergies.
- Have low numbers of blood platelets(which help blood clotting), a bleeding disorder, or are taking anticoagulants (to prevent blood clots).
- Are pregnant or plan to become pregnant.
- Are breastfeeding a child.
- Are taking medications(prescription, over-the-counter, vitamins, or herbal products)
- Have had a heart attack or stroke, have other heart problems, or at high risk of cardiac (heart) events.

Who should generally not take EVUSHELD?
Do not take EVUSHELD if you have had a severe allergic reaction to EVUSHELD or any ingredient in EVUSHELD.

What other prevention choices are there?
Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of EVUSHELD does not replace vaccination against COVID-19. For more information about other medicines authorized for treatment or prevention of COVID-19 go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for more information.
It is your choice to receive or not receive EVUSHELD. Should you decide not to receive EVUSHELD, it will not change your standard medical care.
EVUSHELD is not authorized for post-exposure prophylaxis of COVID-19.

What if I am pregnant or breastfeeding?
If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with EVUSHELD?
Contact your healthcare provider if you 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 or call AstraZeneca at 1-800-236-9933.
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 Healthcare 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 Astrazeneca 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 EVUSHELD**.**
- 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 EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for Coronavirus Disease 2019 (COVID-19)
- By signing this form, I am not waiving any of my legal rights.

_____

Patient Name Printed

_____ _____

Patient/ Caregiver/ Legally Authorized Representative Signature Date and Time

Provider 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.

_____ Select Facility: CMMC, BH, RH

Provider's Printed Name

_____ _____

Provider's Signature Date and Time