CONSENT FOR COVID-19 PRE EXPOSURE PROPHYLAXIS
Tixagevimab and Cilgavimab (EVUSHELD)

Language interpretation and sign language services are available free of charge

Your medical provider has recommended you receive two drugs named tixagevimab and cilgavimab, also referred to as EVUSHELD. You have the option to receive these medications, tixagevimab and cilgavimab, by injection into a muscle, called an intramuscular injection or IM injection. Before you decide whether you would like to receive these medications, your medical provider would like you to review this information. If you decide that you would like to receive these medications, 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.

As your medical provider has discussed with you, tixagevimab and cilgavimab are not used to treat COVID-19 (or SARS-CoV-2) disease, or to prevent infection after a known exposure to COVID-19. Instead, tixagevimab and cilgavimab are used to prevent infection without any known exposure to COVID-19. This is called pre-exposure prophylaxis.

BACKGROUND

Tixagevimab and cilgavimab are investigational medicines for pre-exposure prophylaxis of COVID-19 disease in adults or adolescents (12 years of age or older and weighing at least 88 pounds [40 kg]) who are not currently infected with COVID-19 disease and who have no known recent contact with someone infected with COVID-19 AND

- May not mount a full immune response to COVID-19 vaccination due to immune compromise from a medical condition or immune suppressing medicines OR
- Cannot be vaccinated with any available COVID-19 vaccine according to the approved schedule due history of severe allergic reaction to a COVID-19 vaccine and/or COVID-19 vaccine component(s).

Tixagevimab and cilgavimab are given has two consecutive injections into a muscle (intramuscular or IM injections). The injections are usually administered into each buttocks. Since authorization of EVUSHELD, the recommended dose has increased. Patients who initially received the lower dose should receive a second dose of EVUSHELD (150 mg of tixagevimab and 150 mg of cilgavimab) as soon as possible. Patients who have not received a dose of EVUSHELD should receive the new recommended dose (300 mg of tixagevimab and 300 mg of cilgavimab).

Tixagevimab and cilgavimab are investigational because they are still being studied. There is limited information known about the safety and effectiveness of using tixagevimab and cilgavimab for pre-exposure prophylaxis of COVID-19.

Tixagevimab and cilgavimab are not authorized for post-exposure prophylaxis for prevention of COVID-19 or treatment of COVID-19 disease. Tixagevimab and cilgavimab are not authorized for use in patients who have not completed a COVID-19 vaccination series unless the patient cannot be fully vaccinated due to history of severe allergic reaction to a COVID-19 vaccine and/or COVID-19 vaccine component(s). **Proof of vaccination must be given to your medical provider.**

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

POSSIBLE BENEFITS OF TIXAGEVIMAB AND CILGAVIMAB

It is possible that tixagevimab and cilgavimab may help prevent COVID-19 disease in adults and adolescents who may not have a full immune response to COVID-19 vaccines or who cannot receive COVID-19 vaccines. Use of tixagevimab and cilgavimab does not replace vaccination against COVID-19. There is the possibility that these medicines may be of NO direct benefit to you.

POSSIBLE RISKS AND SIDE EFFECTS OF TIXAGEVIMAB AND CILGAVIMAB

- **Allergic reactions.** Allergic reactions can happen during and after injection of tixagevimab and cilgavimab. Sometimes allergic reactions from tixagevimab and cilgavimab can be serious or life-threatening. <u>You may have an increased risk of allergic reaction with tixagevimab and cilgavimab if you have had a severe allergic reaction to a COVID-19 vaccine.</u> EVUSHELD contains polysorbate 80, which is an ingredient in some COVID-19 vaccines and is similar to an ingredient in other COVID-19 vaccines. Your healthcare provider many consult with a healthcare provider who specializes in allergy and immunology before giving you tixagevimab and cilgavimab if you had a serious allergic reaction to a COVID-19 vaccine. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headaches, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face or throat, rash including hives, itching, muscle aches, dizziness, and sweating.

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PATIENT IDENTIFICATION:

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- **Cardiac (heart) events (less than 1%).** Serious cardiac adverse events have happened, but were not common, in people who received tixagevimab and cilgavimab and also in people who did not receive tixagevimab and cilgavimab 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 tixagevimab and cilgavimab experienced serious heart events than people who did not receive tixagevimab and cilgavimab.
  It is not known if these events are related to tixagevimab and cilgavimab 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. Other side effects reported include **headache** (6%), **tiredness** (4%), and **cough** (3%).

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

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

For more information about risks and side effects, please ask your medical provider. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your provider may give you medications to help lessen the side effects. Some side effects are temporary. In some cases, side effects can last a long time. Sometimes they never go away.

CERTIFICATION AND SIGNATURES

I have read this informed consent form and all of my questions have been answered to my satisfaction by my medical provider. I understand that I have the right to refuse to take this medication(s) for any reason. If I choose not to take this medication(s), this decision will not otherwise affect my status as a patient. I voluntarily consent to take the long-acting antibody medication by intramuscular injection as discussed with my medical provider and as described in this consent form.

CONSENT

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies for pre-exposure prophylaxis of COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization.

DATE: _____ **TIME:** _____

(Applicable for patient and witness as they are done at the same time)

_____
Signature of the Patient

If the patient is unable to personally sign, please indicate reason:

❑ Incapacitated ❑ Minor child ❑_____

_____ _____
Signature of Parent, Personal Representative or Medical Durable Power of Attorney

Printed Name of Parent, Personal Representative or Medical Durable Power of Attorney

_____ _____
Witness of Signature

Printed Name of Witness

If sign language or limited English proficiency interpretive services were utilized:

_____ _____
Interpreter Printed Name

Interpreter Identification Number

PATIENT IDENTIFICATION:

St. Peter's Health

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