VAIL HEALTH

EVUSHELD™ CONSENT FORM

Vail Health includes services of Vail Health Hospital

Name	**FIN**
Phone Number	DOB

BACKGROUND

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
- 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 (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(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).

LIMITATIONS OF AUTHORIZED USE

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.

POSSIBLE BENEFITS

It is possible that EVUSHELD (tixagevimab co-packaged with cilgavimab) may provide pre-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. However, there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF EVUSHELD?

Be sure to discuss your health history, conditions and treatments with your provider. It is important to tell your provider all medications that you are taking. Some medications may interact with EVUSHELD and may cause interactions or serious side effects.

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.

- **Pregnancy: There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. EVUSHELD should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.**
- **Lactation: There are no available data on the presence of tixagevimab or cilgavimab in human milk or animal milk, the effects on the breastfed infant, or the effects of the drug on milk production. Maternal IgG is known to be present in human milk.**

_____***initial As a female, I am not aware that I am pregnant and I am not trying to get pregnant, I am not lactating (nursing).***

- 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.

WHAT OTHER TREATMENT CHOICES ARE THERE?

- FDA may allow for the emergency use of other medicines to help prevent COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.
- It is your choice to be treated or not to be treated with EVUSHELD. Should you decide not to receive this medication or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

- Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of EVUSHELD does not replace vaccination against COVID-19.
- I have had the opportunity to review the Emergency Use Authorization Fact Sheet for Recipients.
- I am aware that there is no guarantee that administration of this medication will improve my condition or prevent my becoming infected with the COVID-19 virus.

AUTHORIZATION TO ADMINISTER the Monoclonal Antibody checked above

❑ **YES**, I wish to receive EVUSHELD medication.

❑ **NO,** I do not wish to receive EVUSHELD medication.

I have read or had explained to me, and I understand and have carefully considered the risks and benefits of receiving EVUSHELD. I have had a chance to ask questions, which were answered to my satisfaction. I hereby release this provider, Vail Health Hospital, its employees and its volunteers from any liability for any results which may occur from the administration of this medication. **I understand that I have the right to refuse to take this treatment(s) for anyreason.**

BY SIGNING THIS CONSENT, I REAFFIRM THAT:

- The information I have submitted is true, complete and correct to the best of my knowledge;
- I have been offered the HIPAA Notice of Privacy Practices & Patient Rights and Responsibilities available through the Vail Health website.

Patient Signature:_____Date: _____

Parent/Legal Guardian:_____Date:_____

If verbal consent is only option (i.e. telehealth), **Provider** to initial receipt of verbal consent: _____ Date: _____

Patient Label