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UK HealthCare Transplant Team

April 2022

Dear Transplant Patient,

In December 2021, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for a new COVID-19 therapy from AstraZeneca called Evusheld. Evusheld is a prevention therapy for certain high-risk individuals that can help protect them from COVID-19 before they are exposed to the virus. Evusheld is the first pre-exposure prophylaxis (prevention) product for COVID-19 apart from vaccines.

Vaccines have proven to be the best defense available against COVID-19. However, there are certain immunocompromised individuals who may not mount an adequate immune response to COVID-19 vaccination or who have a history of severe adverse reactions to a COVID-19 vaccine and therefore cannot receive one and need an alternative prevention option. Evusheld offers protection for these individuals, reducing their risk of developing COVID-19.

Supply of Evusheld is limited at this time. University of Kentucky (UK) HealthCare is prioritizing the use of Evusheld for patients who are most severely immunocompromised and least likely to respond to the vaccine based on guidance provided both in the FDA EUA and by the Kentucky Department for Public Health. Recently, Evusheld eligibility has been expanded to include all transplant recipients who otherwise meet criteria for Evusheld. These criteria include:

1. Not currently infected with COVID-19
2. No known recent exposure to an individual infected with COVID-19
3. Fully vaccinated against COVID-19 for at least 2 weeks

This letter is to inform you of your potential eligibility for Evusheld. A list of commonly asked questions has been included to help you make an informed decision about whether getting Evusheld is right for you. If you are interested in receiving Evusheld or would like to learn more about Evusheld therapy, call the Transplant Center at **859-218-6159** and leave a message when prompted.

Sincerely,

Your UK HealthCare Transplant Team

EVUSHELD FREQUENTLY ASKED QUESTIONS (FAQs)

What is Evusheld?

- Evusheld is a combination of two long-acting monoclonal antibodies (tixagevimab co-packaged with cilgavimab) used for prevention, also known as pre-exposure prophylaxis (PrEP), of COVID-19. It is the first monoclonal antibody therapy intended to work as pre-exposure prophylaxis for people who are not yet infected with COVID-19.
- In a study of persons who were at high risk of severe illness, hospitalization, or death from COVID-19 because they were immunocompromised or ineligible to receive a COVID-19 vaccination, Evusheld was shown to reduce the risk of developing COVID-19 compared to those who received a placebo.

What are monoclonal antibodies?

Monoclonal antibodies are laboratory-made molecules that are designed to act like antibodies made by your immune system to fight an infection. Tixagevimab and cilgavimab, the two monoclonal antibodies in Evusheld, work by blocking the virus from attaching to and entering human cells, thus neutralizing the virus and stopping it from causing further infection.

Is Evusheld approved by the U.S. Food and Drug Administration (FDA) to prevent or treat COVID-19?

No. Evusheld is not FDA-approved to prevent or treat any diseases or conditions, including COVID-19. Evusheld is considered an investigational therapy and is approved for use under an emergency use authorization, or EUA. This is similar to how the COVID-19 vaccines were initially made available for use.

If I receive Evusheld for pre-exposure prophylaxis, does this mean I will not get COVID-19?

The antibodies in Evusheld have been demonstrated to have neutralizing activity against COVID-19 and can help defend the body against getting infected. Even if you test positive for COVID-19 after receiving Evusheld, the antibodies can help clear the virus, and they likely help protect you against progression to more severe disease and shorten your recovery time.

How is Evusheld different from the COVID-19 vaccine?

Evusheld can help prevent COVID-19 infection by providing antibodies directly to a person through an injection. These antibodies work similarly to the antibodies a person develops after a COVID-19 illness or vaccination, but instead of your own body producing the antibodies, these antibodies are already formed, ready for action, and are long-acting.

Who can get Evusheld?

- Not everyone is eligible for Evusheld. The therapy is approved only for certain individuals, including immunocompromised adults and adolescents who do not currently have COVID-19 and have not been recently exposed to the virus.
- Evusheld is not a replacement for COVID-19 vaccination. It is required that patients be fully vaccinated to be eligible for Evusheld. Moreover, because Evusheld may reduce the body's immune response to a COVID-19 vaccine, it is recommended that patients wait to receive Evusheld until at least 2 weeks after COVID-19 vaccination. You will be asked for proof of vaccination prior to receiving Evusheld. Patients with a potential contraindication to receiving the COVID-19 vaccination will be reviewed for eligibility on an individual basis.

How is Evusheld given?

- Evusheld is given as two intramuscular injections (one injection for each medication). One is given immediately after the other, one into each of your buttocks. Patients are observed for 1 hour after receiving the injections.
- You may need additional doses of Evusheld for ongoing protection. Viruses can change over time (mutate) and develop into a slightly different form 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 COVID-19 variants are present in the future.

What are the common side effects of Evusheld?

- As with all medications, Evusheld may cause side effects, most being mild to moderate. Headache, feeling tired, and cough were the most common side effects during clinical trials.
- Because it is given by intramuscular injection, it can also be normal to experience some discomfort, swelling, bruising, or bleeding at the site of injection.

- It is recommended that patients be clinically monitored and observed for at least 1 hour after receiving Evusheld in case of an allergic reaction.

Can I get Evusheld instead of a COVID-19 vaccine? Do I still need to get a booster dose of the vaccine if I have gotten Evusheld?

Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Transplant patients should follow the Centers for Disease Control and Prevention's (CDC's) guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised, including getting a booster dose when they are eligible.

I recently received a COVID-19 vaccine. When can I get Evusheld?

Evusheld may reduce your body's immune response to a COVID-19 vaccine. If you recently received a COVID-19 vaccine, you should wait to receive Evusheld until at least 2 weeks after vaccination.

If I need to get a COVID-19 booster shot after Evusheld, how long do I have to wait after getting Evusheld to get the booster?

COVID-19 vaccination does not need to be delayed after receiving monoclonal antibody therapy, including Evusheld.

If I test positive for COVID-19 or am exposed to someone with COVID-19, can I receive Evusheld?

- Evusheld is not authorized for treatment of COVID-19 or for post-exposure prophylaxis following COVID-19 exposure.
- If you were recently infected with COVID-19, you may be eligible to receive Evusheld after recovery from the acute illness and once you have been released from isolation.
- If you have been recently exposed to COVID-19, you may be eligible to receive Evusheld once you have been released from quarantine and are asymptomatic with negative test results.

If I already had COVID-19 and recovered, am I protected by natural immunity, or should I still get Evusheld?

- Even if you have had COVID-19 previously, you are still at risk for reinfection, and Evusheld can provide additional protection against reinfection.
- Patients who are immunocompromised may not develop antibodies to COVID-19 at all, whether in response to natural infection or to COVID-19 vaccines. Even for those who do, that antibody response decreases, or wanes, over time. Over a period of time, your level of antibodies can decrease below a level that provides effective protection. When antibodies decrease below this threshold of protection, you may become more vulnerable to severe illness. We do not yet know what the threshold of protection for antibodies is for COVID-19 or how long it takes these antibodies to wane. Moreover, as new variants have emerged, they have become more capable of evading our bodies' defenses, and antibodies developed for one strain of the COVID-19 virus may not be as effective against new variants. By combining two potent antibodies with different and complementary activities against the virus, Evusheld was designed to evade potential resistance with the emergence of new COVID-19 variants.

I had a positive COVID-19 antibody test. Should I still get Evusheld?

The short answer is 'yes.' A positive antibody test indicates that an immune response has occurred and can help identify someone who has had COVID-19 in the past or has been vaccinated against COVID-19. Currently authorized COVID-19 antibody tests, however, are not validated to evaluate specific immunity or protection from COVID-19 infection. In fact, individuals can have neutralizing antibodies against COVID-19 (the antibodies thought to be key for protection against future infection) and still get infected. There are studies underway to better understand the antibody response following COVID-19 infection. These studies look to answer such questions as: Which specific antibodies are protective against COVID-19 reinfection? How high do their levels need to be? How long will they provide a reliable defense? In the meantime, however, we know that higher antibody levels, specifically higher neutralizing antibody levels, are better.

How much does Evusheld cost?

Currently, Evusheld is provided by the federal government at no charge to you. However, this could change. Healthcare providers administering Evusheld may bill insurance providers for the cost of administering the medication.