COVID-19 Monoclonal Antibody Treatment (Casirivimab and Imdevimab)
Educational Material and Consent Form

Patient name _____

Facility name_____

Name of provider conducting informed consent_____

Facts about the COVID-19 Emergency Use Authorization (EUA)

Coronavirus is the virus that causes a disease called COVID-19. The virus is passed from person to person mostly by small droplets. These droplets come from the nose or mouth when an infected person coughs, sneezes, or speaks. Some people who are infected have no symptoms. Others have mild symptoms such as a cough and extreme tiredness. Other people have severe problems and may even die. COVID-19 has caused a worldwide pandemic.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for two drugs called Casirivimab and Imdevimab. With an EUA, drugs are not reviewed in the same way as an FDA-approved or cleared product. The FDA may grant an EUA when certain standards are met, for instance, when there are no other choices for treating a health problem like COVID-19. The FDA issues EUAs based on scientific proof that shows the product is likely to be safe and effective.

These two monoclonal antibodies are being studied to treat COVID-19 in non-hospitalized patients with mild to moderate symptoms of COVID-19 who are at high risk for severe COVID-19 problems and/or a hospital stay. The drugs are being studied in patients who are not in the hospital. They must be 12 or older and weigh at least 88 pounds, have a positive COVID test, treated within 10 days of symptom onset, not needing oxygen therapy due to COVID-19. Because the drug is still being studied, there is limited information on how safe or effective it is. After this drug treatment has been used on more people, additional side effects may be noted.

Risks and Common Problems

There are risks linked to this treatment, which include but are not limited to:

Allergic reaction: All kinds of allergic reactions can happen; You could have a minor reaction, such as a rash, or a severe reaction, such as swelling of your lips, face, or throat; A severe allergic reaction is a medical emergency that can cause death.

Changes in your heartbeat

Chills, fever, shivering, muscle aches, and headache

Itching

Low blood pressure and dizziness

Nausea and vomiting

Shortness of breath or wheezing

Sweating

All drugs can cause side effects. Problems that are not expected may happen. These problems may be life threatening. If you have any severe symptoms after the treatment, seek medical attention immediately.

Other Choices

If you decide not to take the Casirivimab and Imdevimab treatment, then you may have other choices. The FDA may grant emergency use for other drugs to treat people with COVID-19. Your doctor may also talk with you about clinical studies you may be able to join.

More Facts

Casirivimab and Imdevimab treatment is not appropriate for patients who are already in the hospital or need increased oxygen therapy due to COVID-19.

It is possible that this treatment could reduce your immune response to a COVID-19 vaccine. The Centers for Disease Control (CDC) recommends waiting 90 days before getting a COVID-19 vaccine.

You will get both drugs at the same time through a vein. This process will take about one hour. You will be given one dose and will be monitored for at least one hour after the treatment.

Tell your doctor if you:

- have needed oxygen due to COVID-19 or on home oxygen;
- are pregnant or plan to become pregnant;
- are breastfeeding (lactating) or plan to breastfeed;
- have any serious health conditions, or;
- are taking any drugs (prescription, over-the-counter, vitamins, and herbals).

After you get this treatment, you will still need to self-isolate, wear a mask, social distance, not share personal items, clean any commonly shared areas, and wash your hands often.

Treatment of Pregnant or Lactating Women

There is limited experience treating pregnant women or breastfeeding mothers with Casirivimab and Imdevimab. It recommends that pregnant women should only be given the drug if the potential benefit outweighs the risk for the patient and her baby.

Consent to Treatment

This consent form told you about the COVID-19 EUA Casirivimab and Imdevimab treatment and its most common risks. If, after reviewing this form, you do not believe that you understand the risks and your choices, then **do not sign the form until all your questions have been answered.**

I have given my provider an updated medical history.

I understand the facts provided to me in this consent form, and it is my choice to receive the COVID-19 Casirivimab and Imdevimab treatment. I give my consent for this treatment. By signing below, I agree that the staff/doctor has discussed the facts in this form with me, that no one has given me any guarantee about the treatment, that I have had a chance to ask questions, and that all of my questions have been answered.

I agree I was given a copy of the Casirivimab and Imdevimab treatment fact sheet today.

I have ___ no known drug allergies **or** ___ the drug allergies listed below:

_____

_____ _____

Signature of Patient or Responsible Party Date and Time

_____

Relationship to Patient (if Responsible Party is not Patient)

_____ _____

Witness Date and Time