SHRIVERS PHARMACY

Patient Consent to Administration of CASIRIVIMAB AND IMDEVIMAB for Patient Diagnosed with COVID-19

This is a consent for emergency use of Casirivimab and imdevimab administration to patients with COVID-19. ***Casirivimab and imdevimab has not been approved by the U.S. Food and Drug Administration (FDA) though the FDA has authorized the emergency use of casirivimab and imdevimab for certain patients 12 years of age or older who have mild to moderate coronavirus disease 2019 (COVID-19) and who are at high risk of progressing to severe COVID-19 and/or hospitalization.***

It is recommended that you receive casirivimab and imdevimab because you have been diagnosed with mild to moderate COVID-19 disease and you are considered to be at high risk of progressing to severe COVID-19 disease and/or being hospitalized. Casirivimab and imdevimab may help reduce the severity of your COVID-19 illness and aid efforts to prevent your COVID-19 illness from worsening and/or resulting in your having to be admitted to a hospital for further treatment. There are currently no approved drugs or other therapeutic agents for the treatment of mild to moderate COVID-19 but casirivimab and imdevimab may present the best available therapy for assisting your body to fight this virus.

Please read this information carefully. It provides important details about the use of casirivimab and imdevimab for patients with mild to moderate COVID-19 disease. casirivimab and imdevimab is regulated by the Food & Drug Administration (FDA), but importantly has not been approved by the FDA. Its use is recommended because you have been confirmed to have mild to moderate COVID-19 disease, and you are considered to be at high risk of progressing to severe COVID-19 disease that may possibly require hospitalization. There is no comparable or satisfactory alternative therapy to treat COVID-19. Please take your time to make your decision. Discuss this matter with your family, friends and healthcare provider before you make your decision. ***Note:*** If you are a family member or legally authorized representative signing this consent form for the patient, "you" in the consent form refers to the patient with COVID-19.

What is casirivimab and imdevimab and why is it recommended that I receive it? You have been diagnosed with disease caused by the SARS-CoV-2 virus, also known as coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory virus that has been associated with a wide range of symptoms such as fever or chills, cough, shortness of breath or difficulty breathing, fatigue, headache, muscle or body aches, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. In more severe cases, symptoms may include failure of the ability to breathe or even death.

You are being asked to consider having casirivimab and imdevimab administered to you subcutaneously to aid in the management of your mild to moderate COVID-19 disease because you are at high-risk of progressing to severe COVID-19 disease that may require your admission to a hospital.

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment

(list continued on page 2)

• Cardiovascular disease (including congenital heart disease) or hypertension
• Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
• Sickle cell disease
• Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
• Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Casirivimab and imdevimab may aid the treatment of COVID-19 in adults and adolescents 12 years of age and older who have mild to moderate symptoms of COVID-19 disease
The FDA grants emergency use authorization to provide availability of a medicine that may help diagnose, treat or prevent a life-threatening disease when no adequate and approved alternatives are available. Casirivimab and imdevimab is a monoclonal antibody that has been scientifically engineered to attach to and destroy an antigen unique to the COVID-19 virus. It is designed to block viral attachment and entry into human cells, thus neutralizing the virus, potentially treating COVID-19. An ***antibody*** is a protein that sticks to a specific protein called an ***antigen***. Antibodies circulate throughout the body until they find and attach to the antigen. Once attached, they can force other parts of the immune system to destroy the cells containing the antigen. Researchers can design antibodies that specifically target a certain antigen, such as one found on COVID-19 virus cells. They can then make many copies of that antibody in the lab. These are known as monoclonalantibodies.Inlimited clinical trials, patients treated with the casirivimab and imdevimab monoclonal antibody showed reduced viral load and rates of symptoms and hospitalization.

It is not known with certainty whether this treatment will or will not help you. This treatment, in uncommon instances, has been known to cause harmful side effects such as anaphylaxis shock (signs of which include, sudden drop in blood pressure and narrowing of airways, resulting in blocked breathing; a rapid, weak pulse; skin rash, nausea and vomiting). The most common reported side effects are nausea, diarrhea, dizziness, headache, severe itching and vomiting. This is one of the only treatments that we have available at this time, but you need to know that it has not yet been proven to work. Because you have been diagnosed with mild to moderate COVID-19 disease and are at high-risk to progress to severe COVID-19 disease which may require hospitalization, and because we do not currently have any better treatment options, we are asking you to consider having casirivimab and imdevimab administered to you as part of the effort to treat your COVID-19 illness.

Is this an approved therapy?
Casirivimab and imdevimab is experimental and is not approved by the Food and Drug Administration (FDA), but is allowed by the FDA for emergency use only.

What is involved in receiving this therapy?
You will be given casirivimab and imdevimab by isubcutaneous injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

What are the possible risks of receiving this therapy?
There is limited information at this point in time concerning the safety of casirivimab and imdevimab. Possible side effects associated with the administration of casirivimab and imdevimab include allergic reactions, the symptoms of which include, fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of the lips, face or throat, rash, including hives, itching, muscle aches, and dizziness.
The risks to pregnant women or breastfeeding mothers are unknown. While the benefit to receiving casirivimab and imdevimab may be greater than the risk from the treatment, you should discuss your specific situation and options with your physician if you are pregnant or breastfeeding.
You may have other side effects that are not known at this time and may include serious injury or pain, disability or death.

What are the possible benefits to receiving casirivimab and imdevimab?

We do not know if casirivimab and imdevimab will be an effective treatment for COVID-19, and you might not experience any benefit. However, this treatment might be effective in improving the likelihood of your recovering from COVID-19 disease and/or reducing the likelihood that your COVID-19 disease may become severe and/or require your hospitalization.

Can I change my mind after I sign this form?
Yes, at any time. You can choose to get this treatment or not. We will always do our best to take care of you.

What other treatment choices are there?
Like casirivimab and imdevimab, FDA may allow for the emergency use of other medicines to treat people diagnosed with COVID-19. Go to www.cdc.gov/COVID19 for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital with 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 with casirivimab and imdevimab. Should you decide not to receive it or stop it at any time, it will not change your standard medical care.

Consent to Receive Casirivimab and imdevimab
By signing this informed consent document, I am agreeing to receive an injection of casirivimab and imdevimab in conjunction with my treatment for mild to moderate COVID-19 disease. I have not given up any of my legal rights or released any individual or institution from liability for negligence. I have discussed with my provider the risks and benefits associated with the administration of casirivimab and imdevimab to me and I have had an opportunity to ask any questions that I might have. I have been advised that there are no FDA approved therapies for the treatment of mild to moderate COVID-19. Casirivimab and imdevimab is NOT approved by the FDA. I have been advized of the significant known and potential risks and benefits of casirivimab and imdevimab, and the extent to which such risks and benefits are unknown.

I acknowledge thatI have been provided a copy of this informed consent document and the Fact Sheet forPatients,Parents and Caregivers Emergency Use Authorization(EUA) Of Casirivimab and imdevimabfor Coronavirus Disease 2019 (COVID-*19) ("Fact Sheet")* prepared and recommended to me for review by the U.S. Food and Drug Administration. I acknowledge that I have had an opportunity to read the Fact Sheet provided to me and have had an opportunity to discuss the same with my provider. The information was read to me or my authorized representative if I am unable to read.

I agree that I have read this form or have had it read to me and I have had any questions or concerns that I have regarding the administration or purpose of casirivimab and imdevimab fully and adequately explained to me and that by signing below, I acknowledge and consent to the administration of casirivimab and imdevimab for the treatment of my COVID-19 illness knowing the risks associated with the emergency use of this drug.
I understand that I will be given a copy of this informed consent document. I further acknowledge that this document was read to me if I made such a request.

_____
Printed Name of Patient

_____ _____
Signature (Patient or Authorized Representative) Date

Consenting Provider

I have explained the treatment to the patient/authorized representative and have answered all questions about this treatment to the best of my ability.

_____
Printed Name

_____ _____
Signature Date and Time

Where applicable:

_____ _____
Interpreter Signature and Language Used Date and Time