PRIMARY MEDICAL

Consent for Monoclonal Antibody Treatment with Regen Cov for COVID-19 infection or exposure for high risk patients

Monoclonal Antibodies are laboratory made proteins that mimic the immune system's ability to fight off harmful antigens, such as viruses. The Monoclonal antibodies in Regen Cov are specifically directed against the spike protein of the SARS-COV-2 virus (COVID-19) and block the viral attachment and entry into human cells.

Monoclonal Antibody (Regen Cov) is a combination of two monoclonal antibodies, Casirivimab and . Imdevimab. Regen Cov administration is utilized for the treatment of mild to moderate coronavirus disease (COVID19) for non- hospitalized adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization as well as for household contacts who are at high risk for progressing to severe COVID-19 (12 years of age and older weighing at least 40 kg) to prevent Covid-19 infection.
Monoclonal Antibody injections are not FDA-approved. However, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of this unapproved product in this pandemic.
Monoclonal Antibodies are administered by intravenous infusion or subcutaneous injection. In our clinic, you will receive subcutaneous injections only.

Potential Benefits: Based on the totality of the scientific evidence available to date, it is reasonable to believe that Monoclonal Antibody (Regen Cov) administration may be effective for the treatment of mild to moderate COVID-19 in certain high-risk patients as specified in the Fact Sheet. When administered to non-hospitalized patients who have a positive SARS Cov2 test and within 10 days of COVID-19 symptom onset as well as for high risk household contacts, Monoclonal Antibody (Regen Cov) administration may reduce viral load, symptoms, and risk of hospitalizations and emergency room visits associated with COVID-19.

Alternative Therapeutic Options: Treatment of COVID-19 includes supportive care for illness symptoms or hospitalization for severe disease.

Possible Risks and Side Effects:
There are limited clinical data available for Monoclonal Antibody (Regen Cov) administration. Serious and unexpected adverse events may occur that have not been previously reported with Monoclonal Antibody (Regen Cov) administration.
There is a potential for serious hypersensitivity reactions, including anaphylaxis, with administration of intravenous Monoclonal Antibodies (Regen Cov). However in the qualifying study for subcutaneous injection of Regen Cov submitted to the FDA, no anaphylaxis was reported.
These are not all the possible side effects of Monoclonal Antibody (Regen Cov) administration. Serious and unexpected side effects may occur. Monoclonal Antibody (Regen Cov) administration is still being studied so it is possible that not all of the risks are known at this time. Infusion/Injection-related reactions have been observed with the administration of Monoclonal Antibody administration. Signs and symptoms of infusion/injection related reactions may include: headache and injection site reactions such as bruising, itching and swelling.

It is possible that Monoclonal Antibody administration could interfere with your body's own ability to fight off a future infection of SARS-CoV2. Similarly, Monoclonal Antibody administration may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies are being conducted to address these possible risks.

Patients qualify for the therapy if they:

1. Have a positive test for COVID
2. Symptoms started within the past 10 days
3. Have at least one High Risk Criterion
4. Are not hospitalized and are not requiring oxygen or increased oxygen (if they already use oxygen for a chronic condition).

Exposed patients qualify for the therapy if they:

1. Are exposed to COVID from a close contact such as in their household or if they live in a facility that has a current outbreak
2. Are not vaccinated or have a low immune system such that we don't expect the vaccine to be as effective
3. Have at least one High Risk Criterion

High Risk Criterion include:

☐ Age >65	☐ Immunosuppressive disease or treatment
☐ Obesity, BMI >25	☐ Cardiovascular Disease or Hypertension
☐ Latinx/African American	☐ Chronic Lung Disease/Sleep Apnea
☐ Pregnancy	☐ Sickle Cell Disease
☐ Chronic Kidney Disease	☐ Neurodevelopmental Disorder
☐ Diabetes	☐ Former or current smoker

Post Exposure Prophylaxis Criterion also include:

☐ Not fully vaccinated or vaccination is not expected to create full immunity due to immunocompromised condition	**AND** ☐ Close Contact Exposure **OR** ☐ High Risk Exposure/Nursing Homes/Incarcerated

Provider: _____

I have counseled this patient as to the benefits, alternatives and risks involved with infusion of Monoclonal Antibodies, and possible side effects, as described above.

Signature: _____ Date: _____

Patient: _____ **Date of Birth:** _____

I understand the information printed on this form. I have discussed Monoclonal Antibody Infusion, its risks and potential benefits, and my other choices with the attending Provider. I understand Monoclonal Antibody administration is not yet FDA approved for use in COVID19 infection, but is FDA authorized solely for emergency use as determined above. My questions have been answered. and I consent to receive the treatment.

Signature: _____ Date: _____