PRIMARY MEDICAL

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

Instructions to the Referring Provider:

- Review this information sheet with your patient
- Indicate the high risk conditions that apply to your patient/exposed patient
- Complete our basic registration and consent for treatment form
- Email or fax this entire packet to Primary Medical
    - covidresponse@primarymedical.net
    - Fax 805-644-4399
- Primary Medical will contact the patient to schedule the administration

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. Each patient receives a total of 4 injections at their appointment because it is too much volume of medication to inject only in one place. Usually, we inject under the skin of the back of the arms, abdomen or thigh.

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 or 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 one High Risk Criteria
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 one High Risk Criteria

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	☐ Current or Former 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

PRIMARY MEDICAL

Registration, Consent to Treatment, and Authorization to Release Medical Information

Monoclonal Antibody Clinic

Last Name: _____First Name: _____ Middle Name/Suffix: _____

Legal Sex: M / F Date of Birth: _____

Address: _____

City: _____ State: _____ Zip: _____ Country: _____

Patient's Email: _____

Home Number: _____ Mobile Number: _____

Primary Care Physician: _____ Referred By:_____

Demographics

Primary Language (English/Spanish/etc): _____

Race: _____ Ethnicity: _____

Marital Status: _____

Emergency Contact

Name: _____ Relationship: _____

Home Phone: _____ Mobile Phone: _____

Primary Insurance: _____

Subscriber Name: _____ Date of Birth: _____

Member ID number: _____ Subscriber relationship to Patient: _____

Secondary Insurance: _____

Subscriber Name: _____ Date of Birth: _____

Member ID number: _____ Subscriber relationship to Patient: _____

Consent for Treatment: I hereby consent to and authorize the administration of all treatments that may be considered advisable or necessary in the judgment of any physician who examines and treats me. If at any time I disagree with the treatment plan, I may decline against medical advice. You are authorized to furnish a copy of this report to my insurance carrier. **Authorization and Assignment**: I hereby authorize agents of Primary Medical Group to furnish information to any and all medical records concerning my care to physicians, hospital or other healthcare professionals providing care to me at any time. I authorize agents of Primary Medical to obtain my prescription medication history from other health care providers or pharmacies. Additionally I authorize Primary Medical to release any and all medical records concerning my care to Medicare, any insurance carriers, 3rd party review organization carriers or managed care companies concerning my illness and treatments and I hereby assign to the doctor all payments for medical services rendered**.**

_____ _____

Signature of Patient/Responsible party Date

AUTHORIZATION TO RELEASE MEDICAL INFORMATION TO INDIVIDUALS/FAMILY MEMBERS

In accordance with Federal government privacy rules implemented through the Healthcare Portability Act of 1996 (HIPAA), in order for your physician or staff of Primary Medical to discuss your condition with members of your family or other individuals that you designate, we must obtain your authorization prior to doing so. In the event of a critical episode or if you are unable to give your authorization due to the severity of your medical condition, the law stipulates that these rules may be waived.

Check one please:

_____ I do not authorize Primary Medical to release any or all information concerning my medical care to any individual except as set forth above.

_____ I authorize Primary Medical to verbally release any and all information concerning my medical care to the following individual(s):

Name: _____ Name: _____

Relationship to Patient: _____ Relationship to Patient: _____

_____ _____

Signature of Patient/Responsible party Date