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Sabine County HOSPITAL
A MEMBER OF THE PREFERRED FAMILY

# Monoclonal Antibody Infusion Referral & Order Set

ONLY to be administered to outpatients: non-hospitalized, non-oxygen requiring patients, and no increase in baseline oxygen flow rate due to COVID-19 for those on chronic oxygen therapy

Today's Date: _____

## Referring Provider Information

Provider Name: _____ NPI #: _____

Office Name: _____ Provider Phone #: _____

Provider Email: _____ Provider Fax #: _____

## Patient Information

Patient Name: _____ DOB: _____ Age: _____ Cell Phone: _____

Address: _____ City: _____ State: _____ Zip: _____

Email: _____

Emergency Contact: _____ Contact #: _____ Relationship: _____

Date of Onset of Illness (Days of Illness ≤10 days): _____

Check all symptoms present:

| | | | |
|---|---|---|---|
| ☐ Fever | ☐ Malaise | ☐ Nausea | ☐ Loss of taste/smell |
| ☐ Cough | ☐ Headache | ☐ Vomiting | ☐ Shortness of breath |
| ☐ Sore throat | ☐ Muscle pain | ☐ Diarrhea | ☐ Dyspnea on exertion |

Documented positive COVID test performed: ☐ Yes ☐ No or STOP → Not Eligible or see **Post-Exposure Prophylaxis**

* Date of COVID-19 Testing: _____ Test Type: ☐ PCR ☐ Antigen ☐ No Test

Symptoms present <10 days: ☐ Yes ☐ No or STOP → Not Eligible

Patient is ≥12 years old AND ≥40 kg (88 lbs.) ☐ Yes ☐ No or STOP → Not Eligible

$SpO_2$% >93% on RA: ☐ Yes ☐ No or STOP → Not Eligible

If on Oxygen chronically, is on same rate: ☐ Yes ☐ No or STOP → Not Eligible

Stable for home management/care: ☐ Yes ☐ No or STOP → Not Eligible

Has patient ever had a reaction to a biologic medication ☐ No ☐ Yes STOP → Patient must check with provider first

*NIH Definition:* ***Mild Illness:*** *Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.*

***Moderate Illness:*** *Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have saturation of oxygen ($SpO_2$) ≥94% on room air at sea level.*

## Post-Exposure Prophylaxis

Check one of the following as it applies to post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

☐ Not fully vaccinated or not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination AND exposed to individual infected with COVID-19 with close contact per CDC (Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example))

☐ No or STOP: Not Eligible

## Identify High Risk Eligibility Feature(s) Qualifying Patient for mAb Therapy

Check at least one high risk category your patient has meeting Monoclonal Antibody Infusion criteria and is 18 years of age and older:

☐ Diabetes
☐ Pregnancy
☐ Sickle cell disease
☐ Chronic kidney disease
☐ Older age (for example, age ≥65 years old)
☐ High risk Ethnicity Groups (Latino/ Black)
☐ Obesity or being overweight (for example, BMI >25 $kg/m^2$)
☐ Immunosuppressive disease or immunosuppressive treatment
☐ Cardiovascular disease (including congenital heart disease/hypertension)
☐ Having a medical-related technological dependence (i.e., tracheostomy, gastrostomy, or positive pressure ventilation, not related to COVID-19)
☐ Chronic lung diseases (i.e., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
☐ Neurodevelopmental disorders (i.e., cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)

# Monoclonal Antibody Infusion Referral & Order Set

ONLY to be administered to outpatients: non-hospitalized, non-oxygen requiring patients, and no increase in baseline oxygen flow rate due to COVID-19 for those on chronic oxygen therapy

## All sections MUST BE COMPLETED, or patient will not receive therapy!

☐ I, the provider, attest that I have done all the items listed below:

1. Provided the patient with the Casirivimab-Imdevimab Fact Sheet for Patients, Parents, and Caregivers (Regeneron).
    a. Casirivimab-Imdevimab English Patient Fact Sheet available at https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient.pdf
    b. Casirivimab-Imdevimab Spanish Patient Fact Sheet available at https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-patient-spanish.pdf
2. Patient has been informed of alternatives to receiving Casirivimab-Imdevimab.
3. Patient has been informed that Casirivimab-Imdevimab are unapproved drugs that are authorized for use under FDA Emergency Use Authorization
4. Patient expressed verbal understanding of all the information and agreed to proceed with Casirivimab-Imdevimab therapy.

## Eligibility Requirements

☑ Patient is not asymptomatic and has mild to moderate illness as noted by all the following criteria:

- ☑ Is not hospitalized due to COVID-19, OR
- ☑ Does not require oxygen therapy due to COVID-19 and has a saturation of oxygen (SpO2) ≥94% on room air at sea level, OR

☑ Patient is not:

- ☑ Day 10 or greater since symptom onset
- ☑ If pregnant, not cleared with OB/GYN Physician

## Orders for COVID-19 Monoclonal Antibody Therapy

All orders are pre-checked and allow the infusion team to complete all aspects of infusion related care.

☑ Patient may be scheduled at the first available appointment for therapy.

☑ The staff member scheduling and/or the nurse administering the infusion/injection will verify all the following with the patient prior to scheduling and/or infusion/injection:

- ☑ The provider gave and reviewed the Casirivimab-Imdevimab Fact Sheets for Patients, Parents, and Caregivers with the patient or with the parents or caregiver of the patient.
- ☑ The provider informed the Patient, Parents, or Caregivers of alternatives to receiving Casirivimab-Imdevimab therapy and that Casirivimab-Imdevimab are unapproved drugs that are authorized for use under the FDA Emergency Use Authorization.
- ☑ The Patient has expressed understanding of all the information and has verbally agreed to proceed with Casirivimab-Imdevimab therapy.

☑ Notify the provider if the patient no longer meets criteria for therapy or if there are any other clinical concerns such as rapidly deteriorating condition.

**PERIPHERAL IV START PANEL – FOR IV INFUSION ONLY:**

- ☑ Start Peripheral IV line
- ☑ Sodium Chloride (Normal Saline Flush) 10 mL syringe PRN as needed for line maintenance

**INTRAVENOUS DOSING REGIMEN**

- ☑ **Casirivimab 600mg and Imdevimab 600mg in 100 mL NS IV via 0.22-micron filter**
- ☑ Infuse Normal Saline 50 mL at same rate via the same dedicated line AFTER Casirivimab-Imdevimab infusion completed

**INFUSION MONITORING**

- ☑ Monitor patients' vitals every 15 minutes during infusion for any adverse response (hypotension SBP<90, tachycardia (HR >100) or fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness.
- ☑ Stop infusion for any adverse response
- ☑ Notify Provider of any adverse response

**SUBCUTANEOUS DOSING REGIMEN**

- ☑ **If IV infusion is not feasible due to delay in treatment, then use Casirivimab-Imdevimab Subcutaneous Injection**
- ☑ **Casirivimab 600mg and Imdevimab 600mg SUBCUTANEOUSLY ONCE.** Give as FOUR separate 300 mg consecutive injections at 4 different subcutaneous sites.

**POST-INFUSION/INJECTION MONITORING**

- ☑ Monitor for 1 hour after infusion/injection, completed for any signs/symptoms of adverse reaction (hypotension SBP<90, tachycardia (HR >100) or fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness) and notify provider for any reaction. Vital signs every 30 minutes and PRN based on nursing clinical judgment.
- ☑ ****** If allergic or infusion/injection-related reaction occurs, HOLD infusion/injection AND NOTIFY provider immediately. For severe allergic reactions call the ED******
- ☑ Call ED any severe adverse response (hypotension, angioedema, anaphylaxis, severe bronchospasm)
- ☑ Remove IV and discontinue infusion if no adverse response at end of infusion.

## PRN ORDERS

- ☑ Nausea and/or Vomiting: Ondansetron 4 mg ODT or IV X 1 as needed
- ☑ Headache/Temperature >100.5°F: Acetaminophen 1000 mg PO X 1 as needed
- ☑ Pruritis: Diphenhydramine 12.5 mg IV as needed
- ☑ Heartburn: Maalox Max Strength 1200-1200-120 mg suspension 30mL PO

## ADVERSE REACTION REPORTING

- ☑ Report all adverse events to MEDWATCH
- ☑ Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
- ☑ Complete and submit a postage-paid Form FDA 3500 (https://www.fda.gov/media/76299/download) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or by fax (1-800-FDA-0178), or
- ☑ Call 1-800-FDA-1088 to request a reporting form.
- ☑ Please provide a copy of all FDA MedWatch forms to Regeneron via fax (1-888-876-2736) or email (medical.information@regeneron.com)

## DISCHARGE INSTRUCTIONS

- ☑ Patient should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high tough" surfaces, and frequent handwashing) according to CDC guidelines.
- ☑ This medication is not a substitute for vaccination against COVID-19.
- ☑ It is recommended that after being treated with monoclonal antibodies, you should wait 90 days before getting a COVID-19 vaccine.

**Provider Name (printed):** _____

**Provider Signature:** _____ **Date:** _____

# PATIENT CONSENT FORM FOR COVID-19 TREATMENT PURPOSE OF INFORMED CONSENT

**Casirivimab/Imdevimab (Regeneron)**

As your physician has discussed with you, you have been diagnosed with COVID-19 (or SARS-CoV-2). At the present time, there are few Food and Drug Administration (FDA) approved, or clinically proven therapies for treatment of COVID-19. As new clinical data emerges, local treatment guidelines have been developed and will be updated as new information becomes available. CDC guidelines reflect what is known about therapies that may work against the SARS-CoV-2 virus, have been used to treat other coronaviruses, or may theoretically target the underlying causes of virus- related severe lung conditions that make breathing difficult.

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1),unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization

## TREATMENT

In order for you to be treated with the therapy by the Infusion Team, you must sign this form to show that you agree to the use of investigational or off label treatments, that you have been informed of the benefits and risks of taking such therapies as well as the benefits and risks of declining or refusing such use. The Infusion team will annotate the monoclonal therapy available below for your encounter and the particular therapy chosen is based upon availability. You will be provided a patient informational handout regards the specific monoclonal antibody infusion before the infusion begins. **You have the right to refuse to take this treatment(s) for anyreason.**

## BACKGROUND

Regeneron is an investigational medicine which is a monoclonal antibody used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. The FDA has issued an Emergency Use Authorization (EUA) to permit the use of this unapproved medication. Clinical trials are ongoing to study its safety and efficacy.

## POSSIBLE BENEFITS

It is possible that the medications listed above may help to control your symptoms, slow, or stop the growth of the virus, shorten the duration, or lessen the severity of the illness in you. Possible benefits primarily include improvement in lung function (ability to breathewithout assistance) and normalization of blood pressure. However, there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse.

## POSSIBLE RISKS AND KNOWN SIDE EFFECTS

It is possible that the medication prescribed may not improve your symptoms and not shorten the duration nor severity of the illness. It is possible that the medication will unexpectedly interfere with your ability to improve, hasten damage to the lungs or other organs, andshorten your life.

**Regeneron**

There is limited clinical data available for these treatments and unexpected adverse events may occur that have not been previously reported. Side effects may include allergic reactions and injection site reactions. It is possible that these treatments could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. These treatments may also reduce your body's immune response to a vaccine for SARS-CoV-2. If you receive this therapy, it could reduce or delay your response to any COVID-19 vaccine for up to 90 days following the infusion and should consider waiting 90 days for a COVID-19 vaccine. Alternatives: There are few approved therapies for the treatment of COVID-19 specifically. Medical care relies on helping the patient through the many complications. Most hospitalized patients survive their disease with standard medical care

*List side effects/risks:* **Nausea** (3%) * **Dizziness** (3%) **Headache** (3%) **Pruritus** (2%) Immediate nonserious hypersensitivity (2%) **Diarrhea** (1%) * **Vomiting** (1%). Serious side effects: anaphylaxis (<1%), Low Blood Pressure (<1%), Wheezing (<1%).

For more information about risks and side effects, please ask your physician. Please be advised that not all risks and side effects in thecontext of COVID-19 are known. Your physician may give you medication to help lessen the side effects. Some side effects are temporary. In some cases, side effects can be serious and can last a long time. Sometimes they never go away.

## CERTIFICATION AND SIGNATURES

I have read this informed consent form and all my questions have been answered to my satisfaction by my physician. I understand that I have the right to refuse to take this medication(s) for any reason. If I choose not to take this medication(s), this decision will not otherwise affect my status as a patient. I voluntarily consent to take the monoclonal antibody medication by infusion as discussed withmy physician, and infusion team members as described in this consent form.

**CONSENT**

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1),unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization.

Patient Name: _____

Patient Signature: _____ Date: _____ Time: _____

*If patient is a minor; or is unable to sign, Indicate reason (ex: patient in COVID isolation)*

Name of Person Signing for Patient: _____

Signature of Person Signing for Patient: Date: _____ Time: _____

Name of Witness: _____

Signature of Witness: _____ Date: _____ Time: _____

Witness to complete for translations (if applicable)

Translated by: _____ Language Used: _____

Relationship to Patient: _____ Date: _____ Time: _____