Monoclonal Antibody Algorithm
8/26/21

(These are straight from the FDA EUA)

Criteria for Identifying High Risk Individuals:
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)
- 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
- 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))

Exclusion Criteria:
- Hospitalization
- Oxygen use or Increase use of oxygen due to Covid
- Weight < 40 kg, 88 lbs

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Covid-19 Symptoms for less than 10 days

- No

Patient has at least one of the defined risk factors

- No

Does the patient have any exclusion criteria?

- Yes

Covid PCR or Antigen

- Positive

Give patient information
If consents
Give Monoclonal Antibody

- Negative

Do Not Give Monoclonal Antibody Cocktail

- Yes

No

No

Yes

Yes

Yes

No
You are being given a medicine called REGEN-COV (casirivimab and imdevimab) for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?
COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab and imdevimab)?
REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
  - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson’s Janssen vaccine]), or,
  - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions).
conditions, including someone who is taking immunosuppressive medications), and

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 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). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, or
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the “What is an Emergency Use Authorization (EUA)?” section at the end of this Fact Sheet.

WHO SHOULD NOT TAKE REGEN-COV?
Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?
- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the
tissue just under the skin (subcutaneous injections). Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
  - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.

- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
  - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.

- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.
WHAT OTHER TREATMENT CHOICES ARE THERE?
Like REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used to treat people 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 to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?
Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?
- Ask your health care provider.
- Visit www.REGENCOV.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made REGEN-COV (casirivimab and imdevimab) available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.
REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

**REGENERON**
Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

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Revised: 07/2021
Monoclonal Antibody
Provider Verification and Patient Consent to Treatment

Patient Name: ___________________________  Account #: ___________________________
Primary Care Provider: ___________________  Referred by: ___________________________

Provider Verification:
- [ ] I have evaluated the patient identified herein and reviewed the lab results provided. This patient has at least one Risk factor and a documented Positive PCR or Antigen test for Covid-19.

Allergies: ___________________________

PCR positive or negative: ___________ Date: ___________
Antigen positive or negative: ___________ Date: ___________

Risk Factors – Please check all that apply (these are straight from the FDA EUA)

- Older age (for example, age ≥ 65 years)
- 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
- 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))

- Based on these findings, my patient IS at high risk for progression to severe COVID-19 and IS a candidate for Monoclonal Antibody Therapy.

Preferred Outpatient Infusion Center:
- Bristol Regional Medical Center (Bristol, TN)
- Holston Valley Medical Center (Kingsport, TN)
- Unicoi County Hospital (Erwin, TN)
- Johnston Memorial Hospital (Abingdon, VA)
- Lonesome Pine Hospital (Big Stone Gap, VA)
- Russell County Hospital (Lebanon, VA)

Signature of provider: ___________________________  Date and time: ___________________________

Consent for Treatment
I have been educated on the indications, potential risks and benefits of Monoclonal Antibody therapy for COVID-19. I have had the opportunity to ask questions related to this therapy and I consent to treatment with Monoclonal Antibody.

Printed name of patient or legal guardian if minor: ___________________________  Date/Time: ___________________________

Patient signature or signature of legal guardian if minor: ___________________________

Monoclonal Antibody+Provider Verification and Consent
Ballad Health, 400 N State of Franklin Road, Johnson City, TN 37604
Form Number new Create 01/05/2021; Updated 8/27/2021
Page 1 of 1

FOR BALLAD HEALTH USE ONLY

Patient Label Here
GEN COVID-19 Monoclonal Antibody Orders

Patient Information

Form No. 3040007057
Date: 08/02/2021 CEOC Approved
OSSC Approved 06/21/2021

GEN COVID-19 Monoclonal Antibody Orders [3040007057]

THIS ORDER SET IS ONLY FOR USE WITH PATIENTS WHO ARE POSITIVE FOR COVID-19 AND NOT HOSPITALIZED.
THIS SHOULD ONLY BE USED FOR PATIENTS 12 YEARS OF AGE OR OLDER AND AT A CURRENT COVID-19 MONOCLONAL ANTIBODIES INFUSION SITE.

Patient must MEET CRITERIA below:

- Mild to moderate symptoms
- Weighing at least 40 kg
- At high risk for progressing to severe COVID-19 and/or hospitalization

Post-Exposure Prophylaxis Use:

- In Adult and Pediatric individuals (12 years of age and older weighing at least 40 kg) for 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 who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and
    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC or
    - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

Yale / New Haven Health System Link
URL: "https://files-profile.medicine.yale.edu/documents/7801c631-3dcc-48fc-a438-3aa18f3b7130"

Casirivimab and imdevimab EUA Approval
URL: "https://www.fda.gov/media/145610/download"

Casirivimab and imdevimab Health Providers EUA Fact Sheet:

Casirivimab and imdevimab Patient and Caregivers EUA Fact Sheet:

CDC growth charts
URL: "https://www.cdc.gov/growthcharts/clinical_charts.htm"

Informed Consent for Monoclonal Antibody Treatment
URL: "MS-7742s.pdf (balladhealth.org)"

Scheduling Referral

COVID-19 OP INFUSION - Virtual Health Enrollment

Date: 08/02/2021 Team Review Date: 03/09/2021
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covid-19 OP INFUSION- Virtual Health Enrollment</td>
<td>Referral Dept - UCH EMERGENCY, Referral Dept Specialty - Emergency Medicine, Referral reason - Specialty Services Required</td>
<td></td>
</tr>
<tr>
<td>Nursing Communication</td>
<td>Routine, Once, Starting S For 1 Occurrences May discharge to home after transfusion complete and vital signs stable, Oncology</td>
<td></td>
</tr>
</tbody>
</table>

**General**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verify Informed Consent for Infusion</td>
<td>Routine, Once, Starting S Procedure: monoclonal antibody infusion Proceduralist Obtained Informed Consent: Oncology</td>
<td></td>
</tr>
</tbody>
</table>

**Code Status (Single Response) (Selection Required)**

- Full Code / Attempt Resuscitation
- DNAR / DNI - Allow Natural Death (Do Not Attempt Resuscitation / Do Not Intubate)
- Do Not Intubate (DNI) (May administer CPR and ACLS protocols but do not intubate.)
- DNAR but May Intubate (No CPR / ACLS, but intubation due to respiratory failure is acceptable.)
- DNAR / Cardiac Medications Only (May administer emergency medications only without CPR or intubation.)
- DNAR / DNI - Comfort Measures Only (Measures include interventions to alleviate the patient's misery short of heroic measures.)

**Nursing / Isolation Orders**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMMUNICATION:</td>
<td>Routine, Until discontinued, Starting S, Oncology</td>
<td></td>
</tr>
<tr>
<td>NOTIFY:</td>
<td>Facility Nursing Supervisor for Enhanced Droplet Plus Eye Protection Isolation Status</td>
<td>Routine, Until discontinued, Starting S, Oncology</td>
</tr>
</tbody>
</table>
### Patient Information

**Date:** 08/02/2021  
**Team Review Date:** 03/09/2021

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**IV Fluids**

<table>
<thead>
<tr>
<th>Insert and Maintain IV</th>
<th>&quot;And&quot; Linked Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Insert and Maintain IV</td>
<td>STAT, Once, Starting S For 1 Occurrences, Oncology</td>
</tr>
<tr>
<td>[ ] Insert Peripheral IV</td>
<td>Routine, Until discontinued, Starting S, Oncology</td>
</tr>
<tr>
<td>[ ] Maintain IV Access</td>
<td>Routine, Continuous, Oncology</td>
</tr>
<tr>
<td>[ ] Saline Lock IV</td>
<td>Routine, Once, Starting S For 1 Occurrences, Oncology</td>
</tr>
<tr>
<td>[ ] sodium chloride 0.9 % flush</td>
<td>3 mL As needed, Intravenous, line care, For 90 Days, Oncology</td>
</tr>
</tbody>
</table>

**Medications**

**COVID-19 Confirmed Treatment (Selection Required)**

Best Practice References Advise:
- Clinically monitor patients during administration and observe for at least 1 hour after administration is completed.

| [ ] COVID-19 virus infection | Diagnosis |
| [ ] acetaminophen (Tylenol) PO / PR | "Or" Linked Panel |
| [ ] Diphenhydramine (Benadryl) oral | 25 mg Every 4 hours PRN, Oral, allergies, for infusion related reactions and/or nausea, For 90 Days, Oncology |
| [ ] Albuterol (Proventil / Accuneb) 0.083 % nebulizer solution | 2.5 mg Every 20 min PRN, Nebulization, wheezing, bronchospasm, For 2 Doses, Oncology  
A second dose may be repeated in 20 minutes, if needed. |
| [ ] Ondansetron (Zofran-ODT) disintegrating tablet | 4 mg Every 1 hour PRN, Oral, nausea, vomiting, For 2 Doses, Oncology  
A second dose may be repeated in one hour, if nausea persists. |
| [ ] Monoclonal Antibody Criteria Review (Pharmacist may interchange route below therapeutics) (Single Response) | |
EXCLUSION CRITERIA:
- Patient hospitalized due to COVID-19
- Patients who require oxygen therapy due to COVID-19
- Patients on chronic oxygen therapy that requires an increase in baseline oxygen flow rate due to COVID-19
- **NOTE**: Extreme Limited Availability

INCLUSION CRITERIA:
- 10 days or less since symptom onset
- Weighing at least 40 kg
- Patient age greater than or equal to 12 years
- At high risk for progressing to severe COVID-19 and/or hospitalization

Notes:
- Extreme limited availability

- casirivimab and imdevimab infusion
  - "Followed by" Linked Panel
  - casirivamab 600 mg and imdevimab 600 mg in sodium chloride 0.9 %
  - 100 mL infusion
  - Once, Intravenous, For 1 Doses, Oncology
  - Total volume 110 mL, infusion over 20 minutes
  - Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of casirivimab and imdevimab" been reviewed?
    - if (answer = No)
      - Please provide additional information why requirement is not met.
  - Has the information in the "Casirivimab and Imdevimab Fact Sheet for Patients and Patients/Caregivers" been provided to the patient/caregiver?
    - if (answer = No)
      - Please provide additional information why requirement is not met.
  - Patient must meet at least one of the criteria below:

- casirivimab and imdevimab injection
  - "Followed by" Linked Panel
  - casirivimab 600 mg and imdevimab 600 mg 10 mL subcutaneous injection
  - Once, Subcutaneous, For 1 Doses
  - Has the "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of casirivimab and imdevimab" been reviewed?
    - if (answer = No)
      - Please provide additional information why requirement is not met.
  - Has the information in the "Casirivimab and Imdevimab Fact Sheet for Patients and Patients/Caregivers" been provided to the patient/caregiver?
    - if (answer = No)
      - Please provide additional information why requirement is not met.
  - Patient must meet at least one of the criteria below:

Administration Instructions:
Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided. DO NOT inject into skin that is tender, damaged, bruised, or scarred. Clinically monitor patients after injections and observe patients for at least 1 hour.

Time: __________ Date: ____________ Physician’s Signature: ________________
Informed Consent for Monoclonal Antibody (MAB) Treatment

Your physician has recommended that you consider receiving monoclonal antibody treatment for COVID-19. This treatment will be casirivimab/imdevimab. **YOU HAVE THE RIGHT TO ACCEPT OR DECLINE THE RECOMMENDED TREATMENT.** We have provided you one or more fact sheets and recommend that you read those fact sheets, and ask additional questions of your healthcare provider if additional clarification is needed.

**By signing the consent form below, you acknowledge that you understand the following:**

1. You have been provided the “Fact Sheet for Patients, Parents and Caregivers” and been given an opportunity to read it.
2. Monoclonal antibody treatment with casirivimab/imdevimab for COVID-19 is voluntary, and made available via Emergency Use Authorizations issued by the United States Food and Drug Administration (FDA).
3. The FDA has made casirivimab/imdevimab (monoclonal antibody) available for treatment of COVID-19 despite the fact that casirivimab/imdevimab are not FDA-approved drugs.
4. The decision to accept monoclonal antibody treatment with casirivimab/imdevimab is voluntary, and you have the right to refuse or decline this therapy. If you decline this treatment, you will still be provided all standard treatments but your condition may deteriorate. Even with the recommended proposed treatment, your condition may deteriorate.
5. You have been informed of alternatives to receiving monoclonal antibody treatment.
6. While there are studies which suggest a potential for benefit, there is no scientifically proven results that this therapy is beneficial.
7. There are risks associated with monoclonal antibody treatment with casirivimab/imdevimab. Adverse events have been reported. All potential risks are not known at this time.
8. After review of available information, the FDA believed that the overall potential benefits appeared to outweigh the potential risks, and with relatively few alternative available therapies, it has made these products available through the Emergency Use Authorization program.
9. Your healthcare provider can offer additional information and answer questions at your request, to supplement the information available in the Fact Sheet provided to you.

The monoclonal antibody treatment that has been recommended for me is:

_________ casirivimab / imdevimab

By signing below, I acknowledge that I have reviewed this document, understand its contents, and agree to receive monoclonal antibody treatment for COVID-19 under the Emergency Use Authorization program discussed above.

Patient printed name: __________________________________________________________________________

Patient signature: ____________________________ Date: ___________ Time: ___________