Patient Consent to Administration of CASIRIVIMAB AND IMDEVIMAB (REGEN-COV) for Patient Diagnosed with COVID-19

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

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 are regulated by the Food & Drug Administration (FDA), but **have not** been approved by the FDA. It is recommended for patients who tested positive for COVID-19 who are experiencing mild to moderate disease ***and*** are considered to be at high risk of progressing to severe COVID-19 disease.

Casirivimab and imdevimab (REGEN-COV) treatment is recommended for patients who recently tested positive for COVID-19 and are experiencing mild to moderate symptoms. Eligible patients include those who are considered to be at high risk of progressing to severe COVID-19 disease and/or being hospitalized. The purpose of REGEN-COV is to help reduce the severity of COVID-19 illness and aid in efforts to prevent worsening of disease as well as reduce the risk of hospital admittance for further treatment. Currently, there are no FDA approved drugs or other therapeutic agents to treat COVID-19. REGEN-COV, through its emergency use authorization, may present as the best available therapy for helping your body to fight this virus.

There is no comparable or satisfactory alternative therapy to treat COVID-19. Please take time to make your decision and consider discussing this matter with your family, friends and healthcare provider. *Note:* If you are a family member or legally authorized representative signing this consent form for the patient, "you" refers to the patient with COVID-19.

What is casirivimab and imdevimab (REGEN-COV) and why is it recommended that I receive it?

REGEN-COV is used for the treatment of SARS-CoV-2 virus, also known as coronavirus disease 2019 (COVID-19). COVID-19 is a respiratory virus 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 severe cases, symptoms may include loss of the ability to breathe or even death.

You may consider having casirivimab and imdevimab administered to you subcutaneously (an injection into the skin) to aid in the management of your mild to moderate COVID-19 disease if 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 (≥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))
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. Casirivimab and imdevimab (REGEN-COV) 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 monoclonal antibodies. In limited clinical trials, patients treated with the casirivimab and imdevimab monoclonal antibodies 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 anaphylactic 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 (REGEN-COV) is experimental and is not approved by the Food and Drug Administration (FDA), but is allowed by the FDA for emergency use only. 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.

What is involved in receiving this therapy?
You will be given casirivimab and imdevimab by subcutaneous 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.

The Medicine Shoppe
Monoclonal Antibody
Treatment Center

1000 Market Street
Bloomsburg, PA 17815
Phone: 570-784-9582
Fax: 570-389-1622

ORDER FORM for COVID-19 Antibody Infusion or Subcutaneous Injection

Step 1: Please complete form and fax to 570-389-1622 along with a copy of positive COVID-19 result and a copy of insurance card if available.

Step 2: Once the completed paperwork has been received, a pharmacy representative will contact the patient to coordinate services as soon as possible.

Patient Name : _____ Date of Birth: _____ Age:_____Sex: _____

Weight: _____ lb Height: _____ in Best contact number: _____

Address: _____

Allergies:_____SSN:_____

Diagnosis (Please select A or B):

A - Mild to Moderate COVID-19 **Date of Symptom Onset:_____**

Indication: Emergency Use Authorization (non-FDA approved) for treatment of mild to moderate coronavirus disease 2019 (COVID-19) in 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 progression to severe COVID-19, including hospitalization or death.

The patient must meet one or more of the criteria below to be considered high-risk. Please check the boxes to indicate the criteria this patient meets:	Limitations of Use. REGEN-COV is NOT authorized for use as treatment in patients:
• Age: ≥65 years of age • BMI ≥25, 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))	• Who are hospitalized due to COVID-19, OR • Who require oxygen therapy due to COVID-19, OR • Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

B - Post-Exposure Prophylaxis **Immunization Status: _____**
Date, if available: _____

Diagnosis B continued, see box on next page

Consent to Receive Casirivimab and imdevimab (REGEN-COV)

By signing this informed consent document, I am agreeing to receive an injection of casirivimab and imdevimab (REGEN-COV) 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 (REGEN-COV) is NOT approved by the FDA. I have been advised 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 that I have been provided a copy of this informed consent document and the Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization(EUA) Of Casirivimab and imdevimab for 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

_____

Date

_____

Signature

B Diagnosis B continued below:

Casirivimab and imdevimab are authorized for use under an Emergency Use Authorization (EUA). The EUA is for the use of the unapproved product. REGEN-COV (casirivimab and imdevimab) are supplied as vials to be administered in adult and pediatric patients (12 years of age and older) who weigh 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.

Inclusion Criteria:	**Limitations of Authorized Use:**
● Not fully vaccinated. Individuals are considered fully vaccinated 2 weeks after their 2nd dose in a 2 dose series or 2 weeks after a single dose vaccine. ● 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 as defined by the CDC OR ● Who are at high-risk of exposure to an individual infected with SARS CoV-2 because of infection of other individuals in the same high-risk institutional setting (for example, nursing homes, prisons)	• Post-exposure prophylaxis is NOT a substitute for vaccination against COVID-19 • REGEN-COV is not authorized for PRE-exposure prophylaxis against COVID-19
● Age: ≥65 years of age ● BMI ≥25, 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))	● Who are hospitalized due to COVID-19, OR ● Who require oxygen therapy due to COVID-19, OR ● Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Medication Ordered: REGEN-COV (casirivimab and imdevimab)
Dose Ordered (Indication Specific):

- ○ 600 mg casirivimab and 600 mg imdevimab (initial dose for treatment or post-exposure prophylaxis)
- ○ 300 mg casirivimab and 300 mg imdevimab (subsequent dosing for continued prophylaxis)

I attest that the patient meets the above criteria and have provided the patient/caregiver with the "Fact Sheet for Patients, Parents, and Caregivers" for casirivimab-imdevimab, informed of alternatives to receiving casirivimab-imdevimab, informed that this medication is an unapproved drug that is authorized for use under the Emergency Use Authorization, and documented all of this in the patient's medical record.

_____ _____

Ordering Provider Signature Date

Emergency Management Orders:

- Diphenhydramine (Benadryl) 25mg PO x 1 for mild allergic reaction; 50 mg po x1 for moderate reaction
- Epinephrine (Adrenalin) 0.3 mg IM x 1 prn severe anaphylactic reaction and call 911

Management of Reaction/Anaphylaxis:

Mild Allergic Reaction (fushing, dizziness, headache, sweating, palpitations, nausea):

- Administer diphenhydramine (Benadryl) - 25mg PO
- Assess vital signs at 5-10minute intervals
- If symptoms subside, resume administration of medication if not completed
- If symptoms persist, notify the prescriber before resuming administration

Moderate Allergic Reaction (chest tightness, shortness of breath, hypotension/hypertension (> 20mmHg change in systolic BP), increased temperature, palpitations, urticaria, fushing)

- Slow or stop medication administration
- Administer diphenhydramine (Benadryl) - 50mg PO or 25mg IM if unable to take PO
- Assess vital signs at 5-10 minute intervals
- If symptoms subside, resume administration of medication if not completed
- If symptoms persist, notify prescriber before resuming administration
- If symptoms worsen, follow severe reaction steps

Severe Allergic Reaction/Anaphylaxis (hypotension/hypertension (>40mmHg change in systolic BP), increased temperature with rigors, chest tightness, shortness of breath with wheezing, stridor)

- Stop medication administration
- Call 911
- Position patient on the back or position of comfort if respiratory distress or vomiting occur
- Assess the patient's circulation, airway, breathing, mental status, and skin
- Inject epinephrine 0.3mg in the anterolateral aspect of the thigh. Repeat in 5-10 minutes if needed
- Administer CPR if needed at any time
- Monitor vital signs at 5-10 minute intervals until arrival of EMS

Monitoring

- Document name of medical professional administering the medication
- Document Vital Signs: Temperature, HR, BP, RR, Pulse Ox taken before medication initiation; immediately after medication administration; and 1 hour post medication administration
- Medical professional to monitor patient 1 hour post medication administration
- Document time of medication administration
- Schedule patient follow-up with provider between days 4 and 7 to assess COVID-19 symptoms and treatment tolerance
- Note any adverse reactions - if no healthcare professional is on site, please call the pharmacy at 570-784-9582 for appropriate reporting to MedWatch (will need detail on the date/type of reaction)

Fever Headache Angioedema Throat irritation	Chills Bronchospasm Rash, including urticaria Pruritus	Nausea Hypotension Myalgia Dizziness

ORDERING PHARMACIST, PHYSICIAN or NURSE PRACTITIONER INFORMATION

Pharmacist, Physician or Nurse Practitioner Full Name: _____

_____
NPI

_____
Address

_____ _____ _____
City State ZIP

Office Contact: _____

Phone: _____ Fax: _____

PHARMD/MD/NP Signature:_____

Date:_____

If Verbal Order: Received by: _____ Read back and confirmed on: _____

COMPLETE THE FOLLOWING SECTION DURING MEDICATION ADMINISTRATION

Drug:
REGEN-COV (casirivimab and imdevimab) NDC: 6175-039-01 Lot: _____ Exp: _____

Route of Administration:

- Subcutaneous Injection (total volume of 10ml)

Person Administering Medication Full Name: _____

Date of Service: _____

Medication Administration Started: _____

Medication Administration Stopped: _____

Vital Sign	Prior to Medication Administration	Immediately After Medication Administration	1 Hour Post Medication Administration
Temp			
HR			
BP			
PulseOx			

Patient Follow-Up Phone Appointment Date: _____

The Medicine Shoppe PHARMACY

570-784-9582
1000 SOUTH MARKET STREET · BLOOMSBURG, PENNSYLVANIA 17815

Attention: Dr. _____ Fax#:_____

The following patient has received REGEN-COV (casirivimab and imdevimab) COVID-19 Antibody Treatment

	Treatment - 600mg casirivimab and 600mg imdevimab
	Post-exposure Prophylaxis - 600mg casirivimab and 600mg imdevimab

Date	Patient	Date of Birth

Thank You,

The Medicine Shoppe Pharmacy