Eligible patients can be referred to the UVA COVID-19 clinic for intravenous infusion of investigational monoclonal antibody therapy under an FDA Emergency Use Authorization.

### ELIGIBILITY:

Outpatients with COVID-19 with mild-to-moderate symptoms for fewer than 10 days, without new or increasing oxygen requirement, and at greater risk for developing more serious symptoms that may require hospitalization:

- A body mass index (a body-fat measurement based on height and weight) of 35 or higher
- Chronic kidney disease
- Diabetes
- Diseases that weaken the body's immune system, such as rheumatoid arthritis and multiple sclerosis
- Receiving another treatment that weakens the immune system
- Age 65 and older
- Age 55 and older with cardiovascular disease, high blood pressure, chronic obstructive pulmonary disease (COPD) or other chronic respiratory diseases

#### **REFERRAL:**

To initiate a referral for monoclonal antibody at UVA, please call the UVA hospital operator at 434.924.0000 and ask for the COVID-19 MD provider to be paged at PIC#9007. As therapy should be administered as soon as possible after a positive test result and within 10 days of symptom onset, it is recommended that patient referrals are made as soon as possible to allow time for infusion center clinician review and scheduling. After approval is obtained, the referring provider should complete this form and fax to **434.243.9800**. The COVID clinic infusion team will review the referral form upon receipt and contact the patient to coordinate services as soon as possible. A telehealth visit will be scheduled prior to infusion, and patient selected for infusion will receive their monoclonal antibodies during an appointment at the UVA COVID-19 Clinic. Infusion appointments typically take three to four hours. Call the COVID-19 clinic 434.982.6843 with questions about referrals.

#### **DEMOGRAPHIC INFORMATION:**

Date of referral	
Patient Name	
Patient DOB	
Preferred Language	
Address	
Best Contact number	

### PERTINENT MEDICAL INFORMATION:

Please include any additional information re: patient's health history and medication history. You may free text here or you attach a document that includes current problem list, health history (major surgeries, major illnesses), current medication list, and medication/food allergies.

#### MONOCLONAL ANTIBODY ELIGIBILITY CRITERIA:

Age:	years	BMI:	kg/ m2	weight:	kg	
SARS-CoV2	2 Test Result (p	please include co	py of result): $\Box$ PCR $\Box$	Antigen 🗆 positive 🗆	negative 🗆	pending Date:
SARS-CoV2	2 symptom ons	et date:				

[Note: Antibody therapy is approved for patients with mild to moderate COVID symptoms. Asymptomatic patients likely will not benefit and should not be referred. Patients with severe symptoms should seek emergency medical attention]

SpO2: \_\_\_\_ □ On RA □ On chronic O2 therapy – Baseline O2 Flow rate: \_\_\_\_

Has the patient required an increase in O2 flow rate since becoming symptomatic with COVID?  $\Box$  Yes  $\Box$  No Priority level assigned by COVID-19 MD:  $\Box$  1  $\Box$  2  $\Box$  3  $\Box$ 4

## High Risk for Severe COVID Illness (check all that apply):

 $\Box \operatorname{Age} \ge 65 \text{ y/o}$  $\Box \operatorname{BMI} \ge 35$ 

CKD Disease Stage \_\_\_\_ Baseline [Cr]\_\_\_\_

Diabetes Mellitus

□ Immunosuppressive Disease (e.g. leukemia, lymphoma, HIV if CD4 < 200, etc.) / Specify: \_\_\_\_

□ Immunosuppressive Treatment (e.g. chronic steroid, chemotherapeutic, immunomodulator) / Specify: \_\_\_\_\_\_
 □ Age ≥ 55 y/o and: □ Cardiovascular Disease / Specify (e.g. CAD, cardiomyopathy, arrhythmia, CHF): \_\_\_\_\_\_□ HTN
 □ COPD □ Other Chronic Respiratory Disease (e.g. Pulmonary Sarcoid, Pulmonary Fibrosis) / Specify: \_\_\_\_\_\_

### **REFERRING PROVIDER AGREEMENTS:**

I, the referring provider, am the patient's PCP or other continuity provider and have arranged for the patient to follow up with me/my designee following Antibody infusion. Or I am an ED or Urgent Care provider who will update the patient's PCP about his/her Antibody infusion in order to arrange follow up. If the patient does not have a PCP, I will refer him/her to an appropriate provider and ensure that follow up has been arranged.

### □ Indicates Provider Agreement

I, the referring provider, have advised or will advise the patient that if his/her clinical status declines by the time of the infusion appointment, the treatment may no longer be appropriate for him/her. The patient's clinical status will be re-evaluated at the infusion center at the appointment time. If the patient is deemed in need of hospital care, s/he will be referred immediately.

### □ Indicates Provider Agreement

The COVID Clinic staff will communicate with the referring provider regarding such matters as treatment inappropriateness for patient, ultimate completion of treatment for patient, adverse events, etc..

Name of Referring Site: Name of Referring Provider: Address: Point of Contact: Phone Number: Fax Number: Preferred mode of contact: 
Phone 
Fax

### **RESOURCES:**

There are two Antibody treatments on our formulary. Patients will be scheduled for one or the other treatment based on availability of medications and logistics.

Information about both medications, Casirivimab+Imdevimab or Bamlanivimab, including Fact Sheets and Manufacturer Instructions/Package Inserts for Healthcare Providers and for Patients/Parents/Care Givers, can be found at <a href="https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs">https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs</a> (scroll to section on Drugs and Biologic Products).

# PATIENT EDUCATION MATERIALS:

English: Fact Sheet for Patients, Parents, and Caregivers: Emergency Use Authorization (EUA) of casirivimab and imdevimab for COVID-19 (fda.gov)

English: Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19) (fda.gov)

Spanish: <u>Guía informativa para pacientes, padres y cuidadores Autorización de uso de emergencia (EUA) de</u> bamlanivimab para la enfermedad por coronavirus 2019 (COVID-19) (fda.gov)