To: Medical Staff, Physician Assistants, Advanced Nurse Practitioners

CC: Pharmacy Department

From: Infectious Diseases Division and the Antimicrobial Stewardship Program (ASP)

Date: 8/24/2021

Re: Investigational monoclonal antibody (mAb) treatment for COVID-19 under the FDA EUA

Background: As of August 17, 2021, two anti-SARS-CoV-2 monoclonal antibody (mAb) products currently have Emergency Use Authorizations (EUAs) from the FDA.

- Casirivimab + imdevimab (REGEN-COV™)
- Sotrovimab

Indications:

- Outpatient treatment of mild to moderate COVID-19 in adults 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 (see **table-I**) for progressing to severe COVID-19 and/or hospitalization.

Table I: High Risk Patients

Obesity • Patients age 12 to 17 years, BMI ≥85th percentile for their age and gender based on CDC growth charts • Patients 18 yrs and older, BMI >25 kg/m2
Sickle cell disease
Complex congenital heart disease
Neurodevelopmental disorders
A medical-related technological dependence (trach/vent dependent, gastrostomy)
Asthma, reactive airway or other chronic respiratory disease (CF)
Chronic kidney disease requiring dialysis
Diabetes
Currently on immunosuppressive treatment
Have immunosuppressive disease

Administration:

Clinical data suggest that mAbs are most effective when given early during infection (**symptoms of SARS-CoV-2 lasting ≤ 10 days and positive SARs-CoV-2 viral testing in the last 7 days**).

These drugs are administered in the ambulatory setting and are not authorized for use in patients who are hospitalized due to COVID-19.

Both monoclonal antibodies must be administered in a setting in which healthcare providers have immediate access to medication to treat a severe infusion reaction and ability to activate the emergency medical system if needed. To prevent transmission of COVID-19, Christiana Care has set up a dedicated infusion center for patients requiring administration of these drugs and Nemours will partner with the Christiana Care Virtual COVID Practice to evaluate all eligible patients.

How to initiate a patient on therapy?

Providers who identify a patient who may qualify for mAb should:

- During daytime hours only, contact the Antimicrobial Stewardship Program 302-507-8606 (Monday through Friday) or Infectious Disease on-call on the weekends and holidays to discuss patient eligibility
- If the patient meets eligibility criteria, the requesting provider will contact Christiana Care Virtual COVID Practice (302-428-2121) to schedule an appointment for evaluation.

Please refer to the FDA website for updated fact sheets on monoclonal antibodies: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs