Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

December 1, 2020

Dear Colleague,

We are writing to provide information regarding the announcement of recent United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for investigational monoclonal antibody (mAb) treatments for COVID-19: bamlanivimab (Eli Lilly) and the antibody combination casirivimab/imdevimab (Regeneron). Early data for these therapeutics suggest that they may reduce the risk of hospitalization for people at high risk who have tested positive for COVID-19 and have only mild to moderate symptoms.

The United States Government (USG) has purchased a limited number of doses and is coordinating the weekly allocation of the mAbs therapeutics to state and territorial health departments. The Maryland Department of Health (MDH) is working closely with the Maryland Hospital Association (MHA) and other partners to implement an allocation and distribution process to serve residents across the state as there may be a greater demand than supply of COVID-19 therapeutics. This should be taken into consideration by prescribing providers and communicated to patients. Maryland healthcare providers should communicate to their patients that mAb treatments will be in greater demand than can be satisfied by the supply at the present time.

Five initial regional infusion locations across the state have been designated to allow both temporal and geographic equity distribution for a scarce therapeutic. Future plans for additional subsidiary sites will be based on available supply from the USG. At the time of this letter, the five sites include the following:

- **Region 1**: University of Pittsburgh Medical Center (UPMC) Western Maryland
- **Region 2**: Meritus Health
- **Region 3**: Baltimore Convention Center Field Hospital
- **Region 4**: Tidal Health Peninsula Regional
- **Region 5:** Adventist HealthCare Takoma Park Alternate Care Site

If you have a patient who may benefit from a COVID-19 therapeutic as described below, please follow the referral instructions on page three to refer a patient to one of the currently available infusion sites.

I. Monoclonal Antibody Treatments for COVID-19 Overview

Other than the difference that the Regeneron mAb is a combination treatment, the two EUAs are almost identical with equivalent patient outcomes. The FDA authorizes use of the aforementioned investigational mAbs for treatment of high-risk COVID-19 outpatients (ages

≥12 y/o, weight ≥40 kg) with mild-to-moderate symptoms at risk for progressing to severe disease/hospitalization based on the following criteria:

- Direct SARS-CoV-2 test (e.g., PCR, rapid antigen test) must be positive
- Administered as soon as possible after positive test result and within 10 days of symptom onset
- Provider to review EUA fact sheet, including risks and benefits, with the patient
- Patient/caregiver to be provided with EUA fact sheets
- Administered in a setting where healthcare providers have direct access to medications to manage severe reactions

Please note that bamlanivimab and Regeneron mAbs are not authorized for use in patients:

- 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

High-risk summary definitions are as follows, however all healthcare providers should reference the authorized FDA materials related to the appropriate monoclonal antibody treatment prior to administration.

All Patients (who meet at least 1 of the following criteria):

- BMI ≥35
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease
- Receiving immunosuppressive treatment
- Age ≥ 65 years
- Age ≥ 55 years AND have any of the following: cardiovascular disease, hypertension, COPD/other chronic respiratory disease

Adolescents (age 12-17 years) who meet at least 1 of the following criteria:

- BMI ≥85th percentile for age/gender
- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental disorders (e.g. cerebral palsy)
- Medical-related technological gastronomy, or positive pressure ventilation (not related to COVID-19)
- Asthma, reactive airway, or other chronic respiratory disease that requires daily medication for control

Dosage

- **Bamlanivimab**: The dosage of bamlanivimab in adults and pediatric patients 12 years of age and older weighing at least 40 kg is a single IV infusion of 700 mg bamlanivimab administered over at least 60 minutes.

- **Regeneron mAbs**: The dosage in adults and in pediatric patients (12 years of age and older weighing at least 40 kg) is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single intravenous infusion over at least 60 minutes. Casirivimab and imdevimab solutions must be diluted prior to administration.

II. Infusion Center referral and contact information

If you have a patient that may benefit from a COVID-19 therapeutic as described, please use the standard referral form in the attachments section on page four to refer a patient to one of the currently available infusion sites. It is recommended that patient referrals are made as soon as possible and no later than 7 days after symptom onset to allow time for infusion center clinician review and scheduling. Based on the individual patient's clinical factors and the mAbs supply, infusion site staff will schedule the patient. Given the limited doses and infusion appointment that may be available, it is possible that some referrals may not be able to be accommodated. Referring providers are expected to follow their patients closely by telephone and in person following the infusions.

Region 1: UPMC Western Maryland

- Address: 12500 Willowbrook Road, Cumberland Maryland 21502
- Hours of Operation: Monday through Friday, 8:00 am to 4:30 pm
- Method of referral: Secure email referral form to WMD-COVIDantibody@upmc.edu

Region 2: Meritus Medical Center

- Address: 11116 Medical Campus Road, Hagerstown Maryland 21742
- Hours of Operation: Monday through Friday, 8:00 am to 4:30 pm
- Method of referral: Fax referral form to 301-790-9229

Region 3: Baltimore Convention Center Field Hospital

- Address: W. Conway Street, Baltimore MD 21230
- Hours of Operation: Monday-Friday, 8:00 a.m. to 6:00 p.m.
- Method of referral: Go to umms.org/ICReferral to submit form via secure, HIPAA-compliant upload

Region 4: TidalHealth (formerly known as Peninsula Regional Medical Center)

- Address: 100 E Carroll St, Salisbury, MD 21801
- Hours of Operation: Monday, Wednesday, Friday, 8:00 am to 4:30 pm
- Method of referral: Secure email referral form to COVIDTX@TidalHealth.org or fax to 410-912-4959

Region 5: Adventist HealthCare Takoma Park Alternate Care Site

- Phone hotline: 301-891-5050. *Note: This number is to assist physicians with referral questions. Scheduled patients can also use this line for information prior to an appointment.*
- Address: 7600 Carroll Ave. Takoma Park, MD 20912.
- Hours of Operation: Monday-Friday, 6:30 a.m. to 6:30 p.m.
- Method of referral: Fax referral form to 301-891-6120.

The State of Maryland continues to work to respond to the COVID-19 pandemic, including providing access to important resources for patients. We thank you for your dedication to protecting the health of Maryland residents as COVID-19 regains momentum in our communities.

Sincerely,

Jinlene Chan, MD, MPH
Act. Deputy Secretary
Public Health Services

Howard Haft, MD, MMM, CPE, FACPE
Executive Director
Maryland Primary Care Program

Attachments

Please reference the following FDA materials and review with patients prior to referral. Infusion site clinicians will also review the information with the patient, based on the selected therapeutic.

- Referral form standard for monoclonal antibody treatment across all sites
- Bamlanivimab (LY-CoV55):
  - FDA Fact Sheet for Healthcare Providers: bamlanivimab
  - FDA Fact Sheet for Patients, Parents and Caregivers: bamlanivimab
  - FDA Letter of Authorization: bamlanivimab
  - FDA Frequently Asked Questions for the Emergency Use Authorization for bamlanivimab for the clinical definition of high-risk patients and other critical information.
- Casirivimab and imdevimab
  - FDA Fact Sheet for Healthcare Providers-Regeneron MAbs
  - FDA Fact Sheet for Patients, Parents and Caregivers: casirivimab and imdevimab
  - FDA Letter of Authorization: Regeneron MAbs
  - FDA Frequently Asked Questions for the Emergency Use Authorization for the clinical definition of high-risk patients and other critical information.
- Operation Warp Speed Therapeutics: Monoclonal Antibody Playbook for outpatient administration (Version 2.0)