Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Acting Secretary

December 16, 2020

Dear Colleague,

We are writing to provide updated information regarding the referral process and available Maryland infusion sites for the two FDA EUA-approved 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 that mAb treatments will be in greater demand than can be satisfied by the supply at the present time.

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 three to refer a patient to one of the currently available infusion sites. Initial regional infusion locations across the state have been designated to allow both temporal and geographic equity distribution for a scarce therapeutic.

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.

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 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.

As we increase the number of infusion sites across the state available for patient referrals, we will provide you with updates. Please see the attached Maryland Referral Form for the most current list of sites. 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)