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

January 15, 2021

Dear Colleague,

We are writing to alert you of the availability of two types of monoclonal antibody infusions that have potential benefits to certain patients who have tested positive for the virus that causes COVID-19. 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.

We urge leaders in your facilities administration to inform the medical director and physicians of record of these therapeutic modalities, their known potential benefits, as well as how to obtain these therapies for residents of your facilities.

One of the available products is bamlanivimab, which is manufactured by Eli Lilly. The other product is a combination of two monoclonal antibodies—casirivimab and imdevimab—and is manufactured by Regeneron. Each product is covered by an Emergency Use Authorization (EUA) issued by the federal Food and Drug Administration. Prospective patients must fit the criteria of the EUA. A link to the EUA and many other clinical resources related to these products is provided in the attachments section of this letter.

Administration of either of these products is a medical decision and requires a physician's referral. Please share the clinical information we have provided with all parties you deem appropriate.

Maryland has received a significant supply of these products from the federal government. If you have a patient that may benefit from a COVID-19 therapeutic as described, please contact your pharmacy provider and/or home infusion organization for further instruction, as appropriate. Referring providers are expected to follow their patients closely by telephone and in person following the infusions. If demand for monoclonal antibody treatment exceeds available supply, receiving sites may initiate equitable distribution plans.

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,

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

Aliya Jones, M.D., MBA
Deputy Secretary
Behavioral Health

Attachments

Please reference the following FDA materials and review with patients prior to referral, based on the selected therapeutic.

- 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)