Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

August 26, 2021

Dear Colleague,

I am writing to alert you that the Food and Drug Administration (FDA) has authorized an additional use for the COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab and imdevimab) to include post-exposure prophylaxis. FDA's authorization of a therapeutic product for post-exposure prophylaxis is a significant advancement in the COVID-19 response that supplements vaccination for disease prevention.

The new authorization for REGEN-COV is for post-exposure prophylaxis use ***in adult and pediatric individuals*** (12 years of age and older weighing at least 88lbs) for post-exposure prophylaxis of COVID-19 in individuals who are at ***high risk for progression to severe COVID-19***, including hospitalization or death, ***and*** are:

- ***Not fully vaccinated or who are not expected to mount an adequate immune response*** to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) ***and***
    - Have been ***exposed to an individual infected with Coronavirus*** consistent with close contact criteria per CDC ***or***
    - Who are at **high risk of exposure to an individual infected with Coronavirus** because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

This new authorized use is in addition to the prior expanded authorization of REGEN-COV to treat non-hospitalized patients with mild to moderate COVID-19 in adult and pediatric patients, aged 12 and older, with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. REGEN-COV may be administered as either subcutaneous injection or a single IV infusion. Please refer to the updated Fact Sheets for full details about dosing, administration, and expanded patient eligibility criteria which includes those who are deemed by their care provider to be at high risk.

REGEN-COV is expected to be effective against circulating variants, including the Delta variant. It should be noted that post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19, and REGEN-COV is not authorized for pre-exposure prophylaxis.

We urge leaders in your facility's administration to inform the medical director and physicians of record of this therapeutic and preventive modality, their known benefits, as well as how to

obtain this therapeutic for residents of your facilities. 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.

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 Administration

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
- Regeneron (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