

August 19, 2021

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

On August 2, the Food and Drug Administration (FDA) authorized the first post-exposure prophylaxis for COVID-19 emergency use. This is a welcome announcement as cases due to the Delta variant of COVID-19 are surging across the country. **To ensure timely patient access to this therapy, we recommend that the Department of Health and Human Services (HHS) immediately amend its PREP Act declaration for COVID-19 to allow pharmacists to order and administer REGEN-COV (casirivimab and imdevimab) and future products authorized for time-sensitive COVID-19 prophylaxis or treatment.**

FDA authorized REGEN-COV for post-exposure prophylaxis use in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) 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 SARS-CoV-2 consistent with close contact criteria per CDC, or
- Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)

The emergency use authorization issued by FDA indicates that “for post-exposure prophylaxis, either subcutaneous injection or intravenous infusion can be used.” FDA also recommends administering post-exposure prophylaxis “as soon as possible after exposure to SARS-CoV-2.”¹

When patients access care from a pharmacist, directing the patient to another provider for initiation of prophylaxis would unnecessarily delay treatment, if post-exposure prophylaxis occurs at all. Initiation of therapy is particularly likely to be delayed in rural and underserved communities that lack access to infusion services and other healthcare providers. HHS can support timely administration of prophylaxis by authorizing pharmacists to order and administer REGEN-COV.

¹ Fact Sheet For Health Care Providers: Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab)

Through the immunization training process, pharmacists are trained to administer subcutaneous injections. Each pharmacist and pharmacy providing injections is prepared and equipped to monitor for, and immediately administer appropriate medications, in the case of hypersensitivity reactions.

HHS can also use pharmacists to increase access to monoclonal antibody therapy. Regions in Texas, Louisiana, Florida, and other states with high numbers of hospitalized patients are reporting overwhelmed staff due to a nursing shortage and positive COVID-19 cases among their own workforces. Some states have requested staffing assistance from the U.S. military. Pharmacists are administering monoclonal antibody treatments where scope of practice and other policies allow. Mississippi, recently authorized pharmacists to order and administer this therapy because of the dire capacity situation at hospitals. Authorizing pharmacists to order and administer REGEN-COV, through the PREP Act, will help reduce the strain on our healthcare workforce, which is overwhelmed in COVID-19 hotspots nationwide.

The undersigned organizations urge HHS to use pharmacists to ensure timely patient access to COVID-19 post-exposure prophylaxis and treatment, by authorizing pharmacists to order and administer REGEN-COV and future products authorized for time-sensitive COVID-19 prophylaxis or treatment, consistent with their emergency use authorizations. We also urge HHS to coordinate with payors to ensure adequate reimbursement is available to support access to these services when provided by pharmacists. We welcome the opportunity to work with you to identify conditions under which pharmacists should administer time-sensitive COVID-19 prophylaxis or treatment to our patients.

Sincerely,

American Society of Health-System Pharmacists (ASHP)
Society of Infectious Disease Pharmacists (SIDP)
American Pharmacists Association (APhA)
National Community Pharmacists Association (NCPA)
Academy of Managed Care Pharmacy (AMCP)
American Society of Consultant Pharmacists (ASCP)
National Alliance of State Pharmacy Associations (NASPA)
College of Psychiatric and Neurologic Pharmacists (CPNP)
American College of Clinical Pharmacy (ACCP)
American Association of Colleges of Pharmacy (AACP)
American College of Apothecaries (ACA)
National Association of Specialty Pharmacy (NASP)