The Delaware Division of Public Health, Office of Emergency Medical Services and Hospital Preparedness is issuing this information guide on the administration of EVUSHELD for providers responsible for adult and pediatric patients over 12 years of age, weighing more than 40kg, who have medical conditions that may result in moderate to severe immune compromise, who are unable to mount an adequate immune response to COVID-19 vaccines, and would benefit most from receiving pre-exposure prophylaxis (PrEP) from COVID-19.

Summary

There is currently an outbreak of COVID-19 caused by the SARS-CoV-2 coronavirus. The Secretary of the United States Department of Health and Human Services has declared that a public health emergency has existed since January 27, 2020. Circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic.

The U.S. Food and Drug Administration has issued an Emergency Use Authorization for the emergency unapproved product EVUSHELD. EVUSHELD (tixagevimab co-packaged with cilgavimab) is a long-acting monoclonal antibody currently approved for the PrEP of COVID-19.

There are no adequate, approved, and available alternatives to EVUSHELD for the pre-exposure prophylaxis of COVID-19 for individuals that may not mount an adequate immune response to vaccination or has a history of severe adverse reaction to vaccines or their components.

Background

There is a subset of the population that could benefit from the administration of PrEP to the COVID-19 virus. These individuals are 12 years of age or older, who weigh greater than 40kg and have medical conditions (listed under Recommendations) or are receiving treatments that may result in moderate to severe immune compromise and who are are unable to mount an adequate immune response to COVID-19 vaccines. Current studies show that EVUSHELD lowers the risk of contracting COVID-19 by 77%. Coverage against the virus lasts approximately 6 months. After 6 months there may be a need for redosing.

Recommendations

Patients eligible to receive EVUSHELD must test negative for COVID-19 and have not had a known exposure to an individual infected with SARS CoV-2. The time frame between the known exposure and testing negative is up to the discretion of the provider.

Medical conditions or treatments that may result in moderate to severe immunocompromised or result in the patient not being able to mount an adequate immune response to the COVID-19 vaccines include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Recipient of solid organ transplant and taking immunosuppressives therapy
- Recipient of chimeric antigen receptor or hematopoietic stem cell transplant within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (ex: DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis blockers, and other biologic agents.
- Patients known to have severe adverse reactions to COVID-19 vaccines or their components

Be advised, this is not a substitute for vaccination in individuals for whom COVID-19 is recommended, including individuals with moderate to severe immune compromise.

EVUSHELD can be administered to individuals who have received a vaccine at least two weeks after vaccination.

Dose and Administration

Each EVUSHELD carton contains two vials. One containing 150mg/1.5ml of tixagevimab and one containing 150mg/1.5ml of cilgavimab. Each is to be drawn up in a separate syringe and given as two consecutive intramuscular injections.

Administer each injection at different sites, preferably one in each of the gluteal muscles.

Clinically monitor the patient after the injections and observe for at least one hour.

Adverse Reactions

Most common adverse reactions are headache, fatigue, and cough.

Warnings and Precautions

- Hypersensitivity including Anaphylaxis: Clinically monitor and observe the patient for at least one hour post administration. If signs and symptoms of a clinically significant hypersensitivity or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and supportive care. Initiate emergency medical services (911) if needed.

- Clinically Significant Bleeding Disorders: Give with caution to patients with thrombocytopenia or any coagulation disorders

- Cardiovascular Events: There is a higher proportion of reported myocardial infarction and cardiac failure in patients with a history of cardiovascular disease or have cardiac risk factors

Resources

- https://www.fda.gov/media/154703/download
- https://www.meritushealth.com/documents/covid/Final-EUA-00104-Factsheet-HCP-and-PI_12.20.2021.pdf
- https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/