Emergency Use Authorization (EUA) of EVUSHELD (tixagevimab/cilgavimab)

Investigational monoclonal antibody therapy for PRE-EXPOSURE Prophylaxis of COVID-19

Background

On December 8, 2021, the monoclonal antibody combination, **EVUSHELD** (**tixagevimab/cilgavimab)**, was granted **EUA** by the FDA for use as **pre-exposure prophylaxis** of COVID-19 infections in adults and pediatrics (12 years of age and older weighing at least 40 kg).

This emergency use authorized therapy has narrow criteria for use and therefore it is essential for administrators, providers and ancillary staff to be fully aware of the stringent parameters the EUA establishes for EVUSHELD use and limitations for use. Additionally, the FDA has furnished a fact sheet for providers to guide them in the use of this novel therapy and a mandatory fact sheet for provision to patients/caregivers, for their informed consent to treatment.

Emergency Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved product **EVUSHELD (tixagevimab/cilgavimab)** for the **pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg)**:

- Who are **not currently infected with SARS-CoV-2 AND** who have **not had a known recent exposure to an individual infected with SARS-CoV-2 AND:**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments who may not mount an adequate immune response to COVID-19 vaccination (see next page) **OR**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

Limitations of Authorized Use

EVUSHELD is NOT authorized for use in patients:

- For treatment of COVID-19, OR
- For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.

In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

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Additional Notes

- Although a negative COVID-19 test result is not explicitly required per the EUA Fact Sheet, it should be confirmed an individual is not currently infected or has had a recent exposure:
    - STORM CHASER trial data showed that EVUSHELD did not provide statistically significant protection in study participants exposed within the prior 8 days to individuals with laboratory-confirmed SARS-CoV-2 infection.
- EVUSHELD is co-packaged as two **separate** vials of 150mg/1.5mL of tixagevimab and 150mg/1.5mL of cilgavimab and does not require reconstitution or dilution.
    - A single treatment consists of drawing 1.5mL of each product into **separate** syringes and administering the products INTRAMUSCULARLY within 4 hours of preparation preferably one syringe into each gluteal muscle consecutively.
- A 1 hour post-administration observation period is required.
- Product will be available at no cost through the current state-driven allocation process.
- Vaccines and Timing
    - In individuals who have received a COVID-19 vaccine recently, this product should be administered at least 14 days after vaccination.
    - At this time, a timeframe between receipt of this product and a subsequent COVID-19 vaccine dose has not been established.

Moderate to Severe Immunocompromising Conditions and/or Treatments

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts

Relevant Resources

Healthcare providers, administrators, and others whose professional obligations might involve the prescribing, dispensing, or administration of EVUSHELD (tixagevimab/cilgavimab)are encourage to fully read the FDA FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF EVUSHELD.

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