To: **CAHAN San Diego Participants**
Date: **January 27, 2023**
From: **Public Health Services**

Health Advisory Update #60: Coronavirus Disease 2019 (COVID-19): Evusheld No Longer Authorized for Use

Key Messages

- On January 26, 2023, the Food and Drug Administration (FDA) announced that Evusheld (tixagevimab co-packaged with cilgavimab) is not currently authorized for use in the U.S. until further notice.
- Evusheld was prescribed as pre-exposure prophylaxis (PrEP) for COVID-19.
- The FDA has revised the Emergency Use Authorization (EUA) for Evusheld to limit use when non-susceptible SARS-CoV-2 variants predominate, and current circulating variants are not susceptible.
- Providers should store Evusheld until SARS-CoV-2 variants neutralized by the product become more prevalent.

Situation

According to the most recent Centers for Disease Control and Prevention (CDC) data, more than 90% of current COVID-19 infections in the U.S. are caused by SARS-CoV-2 variants against which Evusheld has reduced activity. The Food and Drug Administration (FDA) has responded by announcing that Evusheld is no longer authorized for emergency use in the U.S.

Background

Evusheld is currently the only option for pre-exposure prophylaxis (PrEP) of COVID-19 and was authorized under Emergency Use Authorization (EUA) for use in immunocompromised individuals who may not mount an adequate response to COVID-19 vaccination and for individuals for whom COVID-19 vaccination is not recommended due to a history of a severe adverse reaction. Evusheld is unlikely to be active against certain SARS-CoV-2 variants. According to the most recent CDC data, these circulating variants are projected to be responsible for more than 90% of current infections in the U.S. On January 26, 2023, the FDA revised the EUA for Evusheld to limit its use to when the combined frequency of non-susceptible SARS-CoV-2 variants nationally is less than or equal to 90%.

Actions Requested

1. Cease administration of Evusheld.
2. Retain and store Evusheld in the event that SARS-CoV-2 variants, which are neutralized by Evusheld, become more prevalent in the U.S. in the future.
3. Store Evusheld in accordance with instructions found in the Fact Sheet for Health Care Providers and the Letter of Authorization.

Resources

FDA announces Evusheld is not currently authorized for emergency use in the U.S. | FDA

Thank you for your participation.

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