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GOVERNMENT OF THE DISTRICT OF COLUMBIA

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MURIEL BOWSER, MAYOR

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Health Alert Notice for District of Columbia Health Care Providers

Emergency Use Authorization Revisions to Evusheld Dosing

SUMMARY

On February 24, 2022**,** The U.S. Food and Drug Administration revised the emergency use authorization (EUA) for Evusheld (tixagevimab co-packaged with cilgavimab) to change the initial dose for the authorized use as pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric patients. Based on the most recent information and data available, Evusheld may be less active against certain Omicron subvariants. The dosing regimen was revised because available data indicate that a higher dose of Evusheld may be more likely to prevent infection by the COVID-19 Omicron subvariants BA.1 and BA.1.1 than the originally authorized Evusheld dose. This health notice provides guidance on the revised dosing criteria for the COVID-19 theraputic, Evusheld.

BACKGROUND

AstraZeneca received initial Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the investigational long-acting antibody (LAAB) combination therapy, Evusheld on December 8, 2021. The EUA allows healthcare providers to administer Evusheld (AZD7442) for pre-exposure prophylaxis (PrEP) of symptomatic COVID-19, prior to exposure to the virus. The drug can provide protection for those not expected to mount an adequate immune response following vaccination, including those who are immunocompromised due to a medical condition or immunosuppressive medications, as well as those individuals for whom COVID-19 vaccination is not recommended. Evusheld is a combination of two long-acting antibodies (tixagevimab and cilgavimab) and is administered by intramuscular (IM) injection.

COVID-19 Variants and Evusheld

Based on the most recent information and data available, Evusheld may be less active against certain Omicron subvariants. Thus, the EUA was updated on February 24, 2022, with a dosing regimen revision based on available data indicating that a higher dose of Evusheld may be more likely to prevent infection by the COVID-19 Omicron subvariants BA.1 and BA.1.1 than the originally authorized Evusheld dose.

Revised Dosing Criteria for Evusheld

Previously, the authorized Evusheld dosage was 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections, with repeat doses every six months while SARS-CoV-2 remains in circulation. The current EUA for Evusheld has **increased the initial authorized dose to 300 mg of tixagevimab and 300 mg of cilgavimab**. Patients who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab **as soon as possible. Health care professionals should contact patients who received the previously authorized Evusheld dose to return for an additional 150 mg tixagevimab and 150 mg cilgavimab dose as soon as possible.**

Reporting Requirements for Evusheld

Administration sites should continue to report their courses of Evusheld on-hand and courses administered within the Health Partner Ordering Portal (HPOP). To account for the new dosing guidance administration sites should report per 300mg units used. Therefore, utilization of a single initial dose of 600mg, per the new guidance, will be tracked as TWO doses administered.

Additionally, as part of the EUA, the FDA requires health care providers who prescribe Evusheld to report all medication errors and serious adverse events considered to be potentially related to Evusheld through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178.

ADDITIONAL RESOURCES

- **Emergency Use Authorization**
  - fda.gov/media/154704/download
- **Health Care Provider Fact Sheets**
  - fda.gov/media/154701/download
- **Patient and Caregiver Fact Sheets**
  - fda.gov/media/154702/download
- **Frequently Asked Questions: FDA EUA for Evusheld (FDA)**
  - fda.gov/media/154703/download
- **MedWatch Adverse Event Reporting Program**
  - fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
- **MedWatch Adverse Event Reporting Form**
  - accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

For questions regarding COVID-19 Therapeutics, please contact DC Health at:
Phone: 1-855-363-0333 (M-Sa 9:00am – 5:30pm) | Email: covid.therapeutics@dc.gov