

County of Santa Cruz

HEALTH SERVICES AGENCY

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Public Health Division

PUBLIC HEALTH ADVISORY

To: Santa Cruz County Healthcare Providers

From: Gail Newel, MD, MPH, County Health Officer

Subject: FDA Revises Evusheld Dosing in EUA

Date: March 1, 2022

Situational Update:

The <u>FDA has revised</u> the emergency use authorization (EUA) for <u>Evusheld (tixagevimab co-packaged with cilgavimab)</u> to increase the initial dose to 300 mg of tixagevimab and 300 mg of cilgavimab.

RECOMMENDATIONS

Healthcare providers should contact patients who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) to return to receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible. Evusheld is authorized for use as pre-exposure prophylaxis (PrEP) for prevention of COVID-19 in certain adult and pediatric patients (12 years of age and older weighing at least 40 kg).

Based on the most recent available data, a higher dose may be more likely to prevent infection by Omicron subvariants BA.1 and BA.1.1 than the originally authorized Evusheld dose. Because it is unclear which SARS-CoV-2 variant or Omicron subvariant will become dominant in the United States over the next few months, recommended timing for repeat dosing cannot be provided at this time.

ADDITIONAL RESOURCES

- NIH
 - COVID-19 Treatment Guidelines, <u>Therapeutic Management of Nonhospitalized Adults with</u> COVID-19
- COVID-19 Therapeutics Locator
- CDC Webinar
 - o https://www.emergency.cdc.gov/coca/ppt/2022/011222 slide.pdf

- Therapeutics overview
 - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overviewof-mAbs-Treatment.aspx
- EUA Documents:
 - o https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Scientific Review Documents:
 - o https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological



Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.