

LAC DPH Health Update: Revisions to Evusheld Dosing



February 25, 2022

This message is intended for all primary care, emergency, and urgent care providers.

Please distribute as appropriate.

Key Messages

- The FDA has revised the emergency use authorization for Evusheld (tixagevimab plus cilgavimab) to increase the dose (from an initial dosing of 150 mg of tixagevimab and 150 mg of cilgavimab to 300 mg of tixagevimab and 300 mg of cilgavimab) due to concerns about lower efficacy against certain Omicron subvariants.
- 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.
- The volume of each injection for the new, higher dose will be larger (3 mL instead of 1.5 mL) This means that the injections should be limited to large muscles on the body that can accommodate this volume (e.g., the gluteal muscles).

Situation

On February 24, the U.S. Food and Drug Administration revised the emergency use authorization for Evusheld to increase the initial dose from 150 mg of tixagevimab and 150 mg of cilgavimab to 300 mg of tixagevimab and 300 mg of cilgavimab. The decision was based on recent data showing that Evusheld may be less active against certain Omicron subvariants and 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.

Patients who have already received the previously authorized dose should receive an additional dose of 150 mg of tixagevimab and 150 mg of cilgavimab as soon as possible to raise their monoclonal antibody levels to those expected for patients receiving the higher dose.

Evusheld is authorized for emergency use as a pre-exposure prophylaxis (PrEP) for prevention of COVID-19 in certain adults and pediatric patients (12 years of age and older weighing at least 40 kg). Health care providers should only administer it to individuals who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to someone infected with SARS-CoV-2.

Evusheld is only authorized for those:

- who have moderate-to-severe immune compromise due to a medical condition or who have received immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination, or
- for whom vaccination with any available approved or authorized COVID-19 vaccine 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).

The duration of protection provided by Evusheld against symptomatic COVID-19 infection may not be as long as was shown in the clinical trial supporting the initial authorization because data came from a time period before the emergence of the BA.1 and BA.1.1 subvariants. Because it is unclear which SARS-CoV-2 variant or Omicron subvariant will become dominant in the United States over the next few months, the recommended timing for repeat dosing is not available at this time.

Actions Requested of Providers

- 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.
- The volume of each injection for the new, higher dose will be larger: 3 mL instead of 1.5 mL. This means that the injections should be limited to large muscles on the body that can accommodate this volume (e.g., the gluteal muscles).
- Providers should review the updated Evusheld FDA Provider Fact Sheet before use.
- Providers who do not currently receive Evusheld but who have eligible patients
 can refer their patients to sites listed on the LAC DPH provider webpage <u>COVID-19 Monoclonal & Antiviral Therapy for Nonhospitalized Patients</u>. Refer to the
 "Procuring Medications for your Patients" section and connect with the listed
 points of contact
- Facilities that are interested in becoming an Evusheld provider or that have other Therapeutics-related questions can contact LAC DPH at <u>DPH-Therapeutics@ph.lacounty.gov</u>.

Additional Resources

- Fact Sheets for Healthcare Providers and Patients/Caregivers on Evusheld
- LAC DPH provider webpage <u>COVID-19 Monoclonal & Antiviral Therapy for</u> Nonhospitalized Patients
- FDA Letter of Authorization for Evusheld
- FAQ on the EUA for Evusheld
- AstraZeneca update on Evusheld

For questions related to Evusheld, please contact DPH-Therapeutics@ph.lacounty.gov

This communication was sent by Seira Kurian, MD, MPH, COVID-19 Therapeutics Lead, Los Angeles County Department of Public Health

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