

NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT
COVID-19 Therapeutics Update: Evusheld
2/28/2022

Background

Evusheld, a combination of two long-acting monoclonal antibodies, has an emergency use authorization as 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). The FDA recently amended the authorized dosing for Evusheld.

Evusheld is only authorized for those who are moderately-to-severely immunocompromised and for those whom COVID-19 vaccine is medically contraindicated due to severe adverse reaction to a COVID-19 vaccine or vaccine component. Evusheld is not authorized for post-exposure prophylaxis or treatment of existing COVID-19 disease.

UPDATED FDA AUTHORIZED DOSING

On February 24th, the FDA amended the authorized dosing for Evusheld. **The FDA has increased the initial authorized dose to 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.** Previously, the authorized Evusheld dosage was 150 mg of tixagevimab and 150 mg of cilgavimab. 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.

- 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).
- Healthcare professionals should ensure that patients are receiving the revised Fact Sheet for Patients, Parents and Caregivers.
 - [Evusheld Patient, Parents and Caregiver Fact Sheet](#)
 - [Evusheld Patient, Parents and Caregiver Fact Sheet \(Spanish\)](#)
- Healthcare professionals should review the updated [Evusheld EUA Fact Sheet For Healthcare Providers](#) and [Evusheld Letter of Authorization](#).

UPDATED FDA GUIDANCE ON TIMING FOR REDOSING

The FDA removed its original recommendation for redosing patients every 6 months while SARS-CoV-2 remains in circulation. The FDA stated that the duration of protection provided by Evusheld against symptomatic SARS-CoV-2 infection may not be as long as was shown in the clinical trial supporting the initial authorization because the clinical trial data came from a time period before the emergence of the BA.1 and BA.1.1 subvariants.

The FDA will continue to monitor variant prevalence closely. The FDA will provide updates with redosing recommendations in the near future once more data are available to determine appropriate timing of redosing (e.g., 3 months or 6 months after the prior dose).¹

Resources for New Mexico Healthcare Systems and Providers

[Evusheld EUA Fact Sheet For Healthcare Providers](#)

[FDA Authorizes Revisions to Evusheld Dosing](#)

[Evusheld Letter of Authorization](#)

[Evusheld Patient, Parents and Caregiver Fact Sheet](#)

[Evusheld Patient, Parents and Caregiver Fact Sheet \(Spanish\)](#)

[CDER Scientific Review Documents Supporting EUA](#)

Additional Information

For questions or to become an Evusheld provider, please contact the New Mexico Department of Health COVID-19 Therapeutics Team at covid.thereapeutics@state.nm.us

To locate Evusheld administration sites, visit <https://cv.nmhealth.org/treatments/>.

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page <https://nm.readyop.com/fs/4cjZ/10b2> Please provide all information requested to begin receiving important health alerts and advisories.

1. [FDA authorizes revisions to Evusheld dosing | FDA](#)